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**TAMBARAM SANATORIUM, CHENNAI - 47**



**THE TAMIL NADU Dr. M.G.R. MEDICAL UNIVERSITY**

**CHENNAI - 32**

**Pre-clinical and clinical study on Kuzhpaanda  
Chooranam for Styptic Activity in the management of  
Perumbadu (Menorrhagia)**

**&**

**Pre-clinical and clinical study on Eraippu Mathirai for  
Bronchodilator Activity in the management of Eraippu  
(Bronchial Asthma)**

**(DISSERTATION SUBJECT)**

**For the partial fulfillment of the  
requirement to the Degree of**

**DOCTOR OF MEDICINE (SIDDHA)**

**BRANCH II - GUNAPADAM**

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## INTRODUCTION

Menstrual disorders are the second most common gynaecological condition resulting in hospital referral and account for 12% of all gynaecological referrals<sup>1</sup>. WHO reports that 18 million women aged 30-35 years perceive their menstrual bleeding to be exorbitant<sup>2</sup>.

Menorrhagia is excessive menstrual blood loss over several consecutive cycles which interfere with the women's physical, emotional, social, material quality of life<sup>1</sup>. About one third of women describe their periods as heavy. One in 20 women aged 30-49 years consult their gynaecologist each year for heavy menstruation<sup>1</sup>. Most patients with menorrhagia are older than 30 years. 10% of these women experience blood loss severe enough to cause anaemia. Iron deficiency anaemia occurs in about two third of women with heavy menstrual bleeding. Nearly 30% of all hysterectomies performed are due to heavy bleeding<sup>2</sup>.

Heavy menstrual bleeding may negatively affect quality of life by limiting normal activities. Women may affect from mood changes and becoming self conscious<sup>1</sup>.

The symptoms of menorrhagia include excessive blood loss, prolonged menstruation and presence of blood clots in menstrual bleeding. In Siddha system of medicine Perumbadu is clinically correlated with Menorrhagia.

Vatham, Pitham and Kabam are the three vital humors and essential factors in the composition and constitution of the human body. When one or the other of the humors combine in such a way as to get dearranged by aggravation or diminution etc disease results. Perumbadu occurs as a result of dearrangement of Pitham humor due to its aggravation.

The medicine "Kuzhpaanda Chooranam" is a classical Siddha formulation which is mentioned in "Athma Rakshamirtham ennum Vaithiyasarasangirakam" (P.No. 431, written by Kandhasamy Mudaliyar) to treat Perumbadu. It contains Venpoosanikkai (Benincasa hispida), Kalmadham (rock alum), Milagu (Piper nigrum), Chukku (Zingiber



officinale), Thippili (*Piper longum*), Kadukkai (*Terminalia chebula*), Thanrikkai (*Terminalia bellirica*), Elam (*Elettaria cardamomum*), Lavangam (*Syzygium aromaticum*), Athimathuram (*Glycyrrhiza glabra*), Seeragam (*Cuminum cyminum*), Chenpagapoo (*Michelia champaca*) and Sarkarai (*Saccharum officinarum*) as its ingredients<sup>3</sup>.

The main ingredient of the medicine Venpoosani (Kuzhpaandam) has coolant action and styptic activity<sup>4</sup>. Seeragam has pitha-naasini action which helps in neutralizing the aggravated Pitham humor. Kadukkai, thanrikkai, and athimathuram possess astringent, haemostatic and demulcent activities<sup>4</sup>.

Kuzhpaanda Chooranam has not been evaluated for styptic activity so far.

Hence the author has selected this herbo mineral preparation to treat perumbadu and to evaluate its styptic activity.

## **AIM AND OBJECTIVE**

### **AIM :**

To evaluate the safety and efficacy of Kuzhpaanda Chooranam for styptic activity in the management of Perumbadu (Menorrhagia).

### **OBJECTIVE:**

#### **PRIMARY OBJECTIVE:**

To evaluate the styptic activity of Kuzhpaanda chooranam for Perumbadu (Menorrhagia) in preclinical studies.

#### **SECONDARY OBJECTIVE:**

- Collection of literature evidences in Siddha aspect and botanical aspects.
- Biochemical Analysis.
- Atomic absorption spectrophotometer.
- High performance thin layer chromatography.
- Clinical study- a pilot study on trial medicine.

## MATERIALS AND METHODS

### STANDARD OPERATIVE PROCEDURES:

### COLLECTION AND AUTHENTICATION OF THE RAW DRUGS:

The raw drugs were procured from indigenous raw drug store in Chennai. The authentication was got from competent authority of the Gunapadam Department, National Institute of Siddha, Chennai.

### INGREDIENTS:

1. Venpoosanikkaai ( <i>Benincasa hispida</i> )	-	1 number
2. Purified Kadukkai ( <i>Terminalia chebula</i> )	-	5.1 gm
3. Purified Thanrikaai ( <i>Terminalia bellirica</i> )	-	5.1 gm
4. Purified Chukku ( <i>Zingiber officinale</i> )	-	5.1 gm
5. Purified Milagu ( <i>Piper nigrum</i> )	-	5.1 gm
6. Purified Thippili ( <i>Piper longum</i> )	-	5.1 gm
7. Purified Athimathuram ( <i>Glycyrrhiza glabra</i> )	-	5.1 gm
8. Purified Elam ( <i>Elettaria cardamomum</i> )	-	5.1 gm
9. Purified Lavangam ( <i>Syzygium aromaticum</i> )	-	5.1 gm
10. Purified Chenpagapoo ( <i>Michelia champaca</i> )	-	5.1 gm
11. Purified Kalmadham (Rock alum)	-	5.1 gm
12. Purified Seeragam ( <i>Cuminum cyminum</i> )	-	5.1 gm
13. Powdered Sugar ( <i>Saccharam officinarum</i> )	-	Equal to the weight of the Chooranam obtained.

### PURIFICATION PROCESS:

Purification of Venpoosanikkai:

The seeds and outer skin layer was removed.

Purification of Kadukkai<sup>6</sup>:

The raw drug was purified by removing the seeds.

Purification of Thanrikaai<sup>6</sup>:

Seeds were removed.

Purification of Chukku<sup>6</sup>:

The raw drug was purified by soaking in the limestone water. The outer layer was removed.

Purification of Milagu<sup>6</sup>:

The raw drug was soaked in buttermilk for 1 hour 15 minutes and then it was roasted.

Purification of Thippili<sup>6</sup>:

The raw drug was purified by soaking in the lemon juice.

Purification of Athimathuram<sup>6</sup>:

The raw drug was washed with clean water. The outer layer was peeled off and cut into small pieces and dried.

Purification of Elam<sup>6</sup>:

It was dried in sunlight.

Purification of Lavangam<sup>6</sup>:

It was dried in sunlight.

Purification of Chenpagapoo:

The petals from the flower were separated and dried.

Purification of Kalmatham<sup>7</sup>:

Raw drug was soaked in milk for 8 days and washed with clean water and dried.

Purification of Seeragam<sup>6</sup>:

It was dried in sunlight.

Purification of Sugar<sup>6</sup>:

Dust was removed and powdered well.

### **PREPARATION OF THE MEDICINE<sup>3</sup>:**

The pumpkin was cut into small pieces and baked with the help of the milk in a baking pan (pittaviyal method ).Then ghee was sprinkled over it and it was fried well and powdered well. Kalmadham was powdered well in the kalvam.All the other purified raw drugs were pulverized by an electric grinder into fine powder separately. Finally all the powdered drugs were mixed thoroughly and sieved by using a fine cloth (vasthira kayam).Then the obtained Chooranam was baked again with the help of the milk in the baking pan. Then it was dried again. Then the powdered sugar was added to the Chooranam. The fine powder was stored in a clean, dry air tight container.

### **LABELLING:**

Name of the preparation : Kuzhpaanda Chooranam

Quantity of the drug : 14 Gms

Date of manufacture : May 7<sup>th</sup> 2012, Aug 14<sup>th</sup> 2012

Dose : 1gm, bd

Adjuvant/ vehicle : Hot water

Indication : Perumbadu

Date of expiry : 3 months from the date of preparation.



வெண்பூசணி



கடுக்காய்



தான்றிக்காய்



சுக்கு



மிளகு



இலவங்கம்



திப்பிலி



ஏலம்



அதிமதுரம்



சீரகம்



சர்க்கரை



சண்பகப்பூ



## KALMADHAM

BEFORE PURIFICATION



AFTER PURIFICATION



## KUZHPAANDA CHOORANAM





## 1. வெண்பூசணிக்காய்<sup>4</sup>

**வேறு பெயர்கள்:** வெண்பூசணி, பெரும்பூசணி, சாம்பல்பூசணி

**பயன்படும் உறுப்பு:** காய்

**சுவை:** இனிப்பு, தன்மை: தட்பம், பிரிவு: இனிப்பு

**செய்கை:** குருதிப்பெருக்கடக்கி, உடலுரமாக்கி

**பொது குணம்:**

பெரும்பூ சணிக்காய்க்குப் பித்தமோ டுட்காய்ச்சல்  
அருஞ்சார நீர்க்கட் டருகல்- மருந்திடுல்  
பித்தசுரம் அஸ்திசுரம் பேய்வறட்சி மேகமும்போம்  
மெத்த அனிலமுறும் விள்.

இதன் சாற்றை இரத்தவாந்தி, மற்றும் உள் உறுப்புகளில் உண்டாகும்  
இரத்தப் பெருக்கு இவைகளுக்குக் கொடுக்கச் சாந்தியாகும். கூஷ்மாண்ட கிருதம்  
பலத்தை உண்டாக்கும்.

**பூசணிக்காய் சேரும் இரத்தப் பெருக்கை கட்டுப்படுத்தும் பிற மருந்துகள்:**

1. தண்ணீர்விட்டான் நெய்: 2 தேக்கரண்டி காலை 1 வேளை சாப்பிட பெரும்பாடு  
நீங்கும்<sup>8</sup>.
- 2.கூழ்பாண்ட லேகியம்: 5-10 கிராம் தினம் 2 வேளை பாலில் உட்கொள்ள வேண்டும்.  
குருதிப்பெருக்கடக்கி செய்கை உள்ளது<sup>9</sup>.
- 3.பூசணி எண்ணெய்: 1 நாளைக்கு 2 வேளை உட்கொள்ள இரத்தமூலம், மூலக்கிராணி  
தீரும்<sup>10</sup>.

## 2.கடுக்காய்<sup>4</sup>

வேறு பெயர்கள்: அமுதம், சேதகி

பயன்படும் உறுப்பு: பழம்

சுவை: இனிப்பு, புளிப்பு, துவர்ப்பு, கசப்பு, கார்ப்பு

தன்மை: வெப்பம்

பிரிவு: இனிப்பு

செய்கை: குருதிபெருக்கடக்கி, துவர்ப்பி

பொது குணம்:

தாடை கழுத்தக்கி தாலு குறியிவிடப்  
பீடை சிலிபதமுற் பேதிமுடம்- ஆடையெட்டாத்  
தூலமிடி புண்வாத சோணிகா மாலையிரண்  
டாலமிடி போம்வரிக்கா யால்.

காமாலை, வெள்ளை, மேகரோகம் நீங்கும்.

கடுக்காய் சேரும் பெரும்பாட்டிற்கான பிற மருந்துகள்:

- 1.ஹரிதகி லேகியம்: 1 பலம் தினம் உண்ண பெரும்பாடு, விப்புருதி தீரும்<sup>11</sup>.
- 2.மஞ்சளாதி குழம்பு: பிரமியம், பெரும்பாடு தீரும்<sup>12</sup>.
- 3.சித்தாதி எண்ணெய்: 5-15 துளிகள் பாலில் சாப்பிட பெரும்பாடு, சூதகவெட்டை தீரும்<sup>8</sup>.
- 4.கதலிகந்த நெய்: வேளைக்கு 1 கரண்டி வீதம் உட்கொள்ள மேகவெட்டை, பெரும்பாடு தீரும்<sup>13</sup>.
- 5.தண்ணீர்விட்டான் நெய்: 2 தேக்கரண்டி 1 வேளை உண்ண பெரும்பாடு தீரும்<sup>8</sup>.

### 3.தான்றிக்காய்<sup>4</sup>

வேறு பெயர்கள்: சதகம், கந்துகன்

பயன்படும் உறுப்பு: பழம்

சுவை: துவர்ப்பு, தன்மை: வெப்பம், பிரிவு: இனிப்பு

செய்கை: உரமாக்கி, துவர்ப்பி

பொது குணம்:

ஆணிப்பொன் மேனிக் கழகும் ஒளியுமிகும்  
கோணிக்கொள் வாதபித்தக் கொள்கைபோம்- தானிக்காய்  
கொண்டவர்க்கு மேகமறும் கூறா அனற்றணியும்  
கண்டவர்க்கு வாதம்போம் காண்.

வெள்ளை, குருதியழல், வளி, தீ குற்றங்களால் வரும் நோய்கள் போம்.

தான்றிக்காய் சேரும் பெரும்பாட்டிற்கான பிற மருந்துகள்:

- 1.கதலிகந்த நெய்:வேளைக்கு 1 கரண்டி வீதம் உட்கொள்ள மேகவெட்டை, பெரும்பாடு தீரும்<sup>13</sup>.
- 2.பஞ்சகவ்விய நெய்:1 கழஞ்சு காலையில் மட்டும் உண்ண பெரும்பாடு, குன்மம் தீரும்<sup>13</sup>.
- 3.நிலப்பனை நெய்:2 கழஞ்சு காலையில் கொடுக்க பெரும்பாடு, சுவாசகாசம் தீரும்<sup>13</sup>.
- 4.தண்ணீர்விட்டான் நெய்: 2 தேக்கரண்டி 1 வேளை உண்ண பெரும்பாடு தீரும்<sup>8</sup>.

## 4.சுக்கு<sup>4</sup>

வேறு பெயர்கள்: அருக்கன், அதகம்

பயன்படும் உறுப்பு: கிழங்கு (உலர்ந்தது)

சுவை: கார்ப்பு, தன்மை: வெப்பம், பிரிவு: கார்ப்பு

செய்கை: பசித்தீத்தூண்டி, அகட்டுவாய்வகற்றி

பொது குணம்:

சூலைமந்தம் நெஞ்செரிப்பு தோமேப் பம்மழலை  
மூலம் இரைப்பிருமல் மூக்குநீர்- வாலகப  
தோடமதி சாரந் தொடர்வாத குன்மநீர்த்  
தோடம்ஆ மம்போக்குஞ் சுக்கு.

வெப்பம், பாண்டு, வயிற்றுக்குத்தல் போகும்.

**சுக்கு சேரும் பெரும்பாட்டிற்கான பிற மருந்துகள்:**

- 1.ராஜஏலாதி சூரணம்: தினம் வெருக்கடி உண்ண பெரும்பாடு, மேகஊறல் நீங்கும்<sup>14</sup>.
- 2.அமிர்த சஞ்சீவி சூரணம்: திரிகடிப் பிரமாணம் ஆவின் நெய்யில் உட்கொள்ள பெரும்பாடு, நீர்க்கடுப்பு தீரும்<sup>3</sup>.
- 3.மேகாதி குளிகை: 1 நாளைக்கு இருவேளை 1 உருண்டை விதம் மண்டலம் உட்கொள்ள பெரும்பாடு, மேகம் நீங்கும்<sup>15</sup>.
- 4.அசுவகந்தி சூரணம்: திரிகடி பிரமாணம் 2 வேளை உண்ண பெரும்பாடு, பாண்டு நீங்கும்<sup>16</sup>.

## 5.மிளகு<sup>4</sup>

வேறு பெயர்கள்: மலையாளி, சருமபந்தம்.

பயன்படும் உறுப்பு: விதை, பழம்

சுவை: கசப்பு, கார்ப்பு, தன்மை: வெப்பம், பிரிவு: கார்ப்பு

செய்கை: முறைவெப்பகற்றி, காறலுண்டாக்கி

பொதுகுணம்: சீதசுரம் பாண்டு சிலேத்துமங் கிராணிகுன்மம்  
வாதம் அருசிபித்தம் மாமூலம் - ஓதுசன்னி  
யாசமபஸ் மாரம் அடன்மேகம் காசமிவை  
நாசங் கறிமிளகினால்.

பயன்கள்: வளி, தீ கபக்குற்றங்கள் அனைத்தையும் நீக்கும்.

**மிளகு சேரும் பெரும்பாட்டிற்கான பிற மருந்துகள்:**

- 1.புஷ்பானுகச் சூரணம்: 2-5 வராகன் தேனில் உண்ண சுபாவமாக ஏற்படும் இரத்தஓழுக்கு மிகுதியாக ஏற்படின் வரும் வியாதிகள் நீங்கும்<sup>17</sup>.
- 2.அரிதகி லேகியம்:1 பலம் தினம் உண்ண பெரும்பாடு, விப்புருதி தீரும்<sup>11</sup>.
- 3.மகாமேக ராசாங்கம்: கொட்டைப்பாக்களவு லேகியம் 2 வேளை 1 மண்டலம் உண்ண பெரும்பாடு, எலும்புருக்கி நோய் தீரும்<sup>15</sup>.
- 4.தாதுபுஷ்டி லேகியம்: 1 வேளைக்கு தேற்றான் விரை பிரமாணம் உண்ண பெரும்பாடு, எரிகுன்மம் நீங்கும்<sup>3</sup>.

## 6.திப்பிலி<sup>4</sup>

வேறு பெயர்கள்: ஆர்கதி, உண்சரம்

பயன்படும் உறுப்பு: காய்

சுவை: இனிப்பு, தன்மை: வெப்பம், பிரிவு: இனிப்பு

செய்கை: அகட்டுவாய்வகற்றி, வெப்பமுண்டாக்கி

பொதுகுணம்:

ஆசனநோய் தொண்டைநோய் ஆவரண பித்தமுதல்  
நாசிவிழி காதிவைநோய் நாட்புழுநோய்- வீசிடுவி  
யங்கலாஞ்ச னஞ்சிதையும் அம்பாய் அழிவிந்தும்  
பொங்கலாஞ்ச நங்கையர் கோட்போல்.

திப்பிலி 5 பங்கு, தேற்றான் விதை 3 பங்கு இரண்டையும் அரைத்து பொடித்து  
கழுநீரில் 4 கிராம் 3 நாள் காலைதோறும் கொடுத்து வர வெள்ளை, பெரும்பாடு தீரும்.

**திப்பிலி சேரும் பெரும்பாட்டிற்கான பிற மருந்துகள்:**

- 1.திராக்ஷாதி கிருதம்: 1 கரண்டி 2 வேளை உண்ண பெரும்பாடு, இரத்தப்பித்தம் தீரும்<sup>6</sup>.
- 2.கதளிகந்த ரசாயனம்: கொட்டைப்பாக்களவு தினம் 2 வேளை சாப்பிட பெரும்பாடு, பிரமேகம் நீங்கும்<sup>15</sup>.
- 3.அமிர்த சஞ்சீவி சூரணம்: திரிகடிப் பிரமாணம் ஆவின் நெய்யில் உட்கொள்ள பெரும்பாடு, நீர்க்கடுப்பு தீரும்<sup>3</sup>.
- 4.சித்தாதி எண்ணெய்: 5-15 துளிகள் பாலில் சாப்பிட பெரும்பாடு, சூதகவெட்டை தீரும்<sup>8</sup>.

## 7. அதிமதுரம்<sup>4</sup>

வேறு பெயர்கள்: அதிங்கம், அட்டி

பயன்படும் உறுப்பு: வேர்

சுவை: இனிப்பு, தன்மை: சீதம், பிரிவு: இனிப்பு

செய்கை: உள்ளழலாற்றி, உரமாக்கி

பொதுகுணம்:

தித்திக்கு மதிமதுரக் குணத்தையெடுத்து ரைக்கில்  
சிரமயக்கஞ் சுரதாகந் திரிதோடங்கள்  
பித்தஞ்சத் திக்குமிது குணமா மதுரதீபனமாந்  
தாதுவுட்டிணமுந் தவிர்க்கும் விழிக்கிதமாம்.

உடல் அனல் தணியும். தீக்குற்றத்தின் வன்மையைத் தாழ்ச் செய்யும். வெப்ப நோய்களின் வன்மையைக் குறைக்கும்.

**அதிமதுரம் சேரும் பெரும்பாட்டிற்கான பிற மருந்துகள்:**

1. அமிர்தசஞ்சீவி சூரணம்: திரிகடிப் பிரமாணம் ஆவின் நெய்யில் உட்கொள்ள பெரும்பாடு, நீர்க்கடுப்பு தீரும்<sup>3</sup>.
2. அட்டசந்த நெய்:1 கழஞ்சு 2 வேளை உண்ண பெரும்பாடு, இரத்தக்கட்டு நீங்கும்<sup>13</sup>.
3. நாவல் நெய்: வேளைக்கு 1 கரண்டி வீதம் உட்கொள்ள பெரும்பாடு தீரும்<sup>3</sup>.
4. பஞ்சகவ்விய நெய்:1 கழஞ்சு காலையில் மட்டும் உண்ண பெரும்பாடு, குன்மம் தீரும்<sup>13</sup>.
5. அசுவகந்தி சூரணம்:திரிகடி பிரமாணம் 2 வேளை உண்ண பெரும்பாடு, பாண்டு நீங்கும்<sup>16</sup>.

## 8.ஏலம்<sup>4</sup>

வேறு பெயர்கள்: ஆஞ்சி, கோரங்கம்

பயன்படும் உறுப்பு: விதை

சுவை: கார்ப்பு, தன்மை: வெப்பம், பிரிவு: கார்ப்பு

செய்கை: அகட்டுவாய்வகற்றி, பசித்தித்தூண்டி

பொதுகுணம்: தொண்டை வாய்கவுள் தாலுகு தங்களில்

தோன்றும் நோயதி சாரம்பன் மேகத்தால்

உண்டை போலெழுங் கட்டி கிரிச்சரம்

உழலை வாந்தி சிலந்தி விஷசுரம்

.....

அண்டை யீளைவன் பித்தம் இவைக்கெல்லாம்

ஆல மாங்கமழ் ஏல மருந்ததே.

அழலை ஆற்றும். கழிச்சல் நோயைப் போக்கும்.

ஏலம் சேரும் பெரும்பாட்டிற்கான பிற மருந்துகள்:

- 1.ஆவாரை நெய்: வேளை ஒன்றுக்கு 1 கரண்டி வீதம் சாப்பிட்டு வர சகலமேக நீரிழிவு, பெரும்பாடு தீரும்<sup>3</sup>.
- 2.ஜம்பு கிருதம்: 1/2-1 கரண்டி 2 வேளை உட்கொள்ள பெரும்பாடு, நீரிழிவு தீரும்<sup>6</sup>.
- 3.இராஜஏலாதி குரணம்:தினம் வெருக்கடி உண்ண பெரும்பாடு, மேகஊறல் நீங்கும்<sup>14</sup>.
- 4.அமிர்த சஞ்சீவி குரணம்:திரிகடிப் பிரமாணம் ஆவின் நெய்யில் உட்கொள்ள பெரும்பாடு, நீர்க்கடுப்பு தீரும்<sup>3</sup>.
- 5.நிலப்பனை நெய்:2 கழஞ்சு காலையில் கொடுக்க பெரும்பாடு, சுவாசகாசம் தீரும்<sup>13</sup>.



## 9.இலவங்கம்<sup>4</sup>

பயன்படும் உறுப்பு:பூ

வேறு பெயர்கள்:திரளி, அஞ்சுகம்

சுவை: விறுவிறுப்பு, கார்ப்பு, தன்மை: வெப்பம், பிரிவு: கார்ப்பு

செய்கை: அகட்டுவாய்வகற்றி, இசிவகற்றி

பொதுகுணம்:

பித்தமயக்கம் பேதியோடு வாந்தியும் போம்  
சுத்தவிரத் தக்கடுப்புந் தோன்றுமோ- மெத்த  
இலவங்கங் கொண்டவருக் கேற் சுகமாகும்  
மலமங்கே கட்டுமென வாழ்த்து.

பயன்கள்: மயக்கம், பேதி, வாந்தி தீரும்.

**இலவங்கம் சேரும் பெரும்பாட்டிற்கான பிற மருந்துகள்:**

- 1.பெரும்பாடு சிந்தூரம்: பணவெடை வீதம் தக்க அனுபானத்தில் கொடுக்க சூலை, பெரும்பாடு தீரும்<sup>3</sup>.
- 2.ஆவாரை நெய்: வேளை ஒன்றுக்கு 1 கரண்டி வீதம் சாப்பிட்டு வர சகலமேக நீரிழிவு, பெரும்பாடு தீரும்<sup>3</sup>.
- 3.கதலிகந்த நெய்: வேளைக்கு 1 கரண்டி வீதம் உட்கொள்ள மேகவெட்டை, பெரும்பாடு தீரும்<sup>3</sup>.
4. மேகராஜாங்க கிருதம்: 1 கரண்டி வீதம் 9 நாள் 2 வேளை உண்ண பெரும்பாடு, எலும்புருக்கி தீரும்<sup>6</sup>.
- 5.மகாமேக ராசாங்கம்:கொட்டைப்பாக்களவு லேகியம் 2 வேளை 1 மண்டலம் உண்ண பெரும்பாடு, எலும்புருக்கி நோய் தீரும்<sup>15</sup>.

## 10.சண்பகப்பூ<sup>4</sup>

பயன்படும் உறுப்பு:பூ

சுவை: கைப்பு, தன்மை: வெப்பம், பிரிவு: கார்ப்பு

செய்கை: உரமாக்கி, சிறுநீர்பெருக்கி

பொதுகுணம்:

வாதபித்தம் அத்திசுரம் மாமேகம் சுத்தசுரந்  
தாதுநட்டங் கண்ணழற்சி தங்காவே- மாதே  
திண்புறு மனக்களிப் பாந் திவ்யமனம்  
சண்பகப் பூவதற்குத் தான்.

வளித்தீ சுரம், என்புச்சுரம், வெள்ளை நீங்கும்.

சண்பகப்பூ சேரும் பெரும்பாட்டிற்கான பிற மருந்துகள்:

- 1.பெரும்பாட்டிற்கு லேகியம்: வேளை ஒன்றுக்கு கொட்டைப்பாக்களவு சாப்பிட பெரும்பாடு, எலும்புருக்கி நீங்கும்<sup>3</sup>.
- 2.மகாமேக ராசாங்கம்:கொட்டைப்பாக்களவு லேகியம் 2 வேளை 1 மண்டலம் உண்ண பெரும்பாடு, எலும்புருக்கி நோய் தீரும்<sup>15</sup>.

## 11.சீரகம்<sup>4</sup>

வேறு பெயர்கள்: பித்தநாசினி, அசை

பயன்படும் உறுப்பு: விதை

சுவை: இனிப்பு, தன்மை: தட்பம், பிரிவு: இனிப்பு

செய்கை: துவர்ப்பி, பசித்தீதுண்டி

பொதுகுணம்: வாயுவொடு நாசிநோய் வன்பித்தம் சேராது  
காயம் நெகிழாது கண்குளிருந்- தூயமலர்க்  
காரளகப் பெண்மயிலே கைக்கண்ட தித்தனையுஞ்  
சீரகத்தை நீதினமுந் தின்.

அழல் போம். தீக்குற்றம் தன்னிலைப்படும்.

சீரகம் சேரும் பெரும்பாட்டிற்கான பிற மருந்துகள்:

- 1.பாண்டு, சோகை முதலிய பித்த வகைகளுக்கு குளிகை: கொட்டைப்பாக்களவு குளிகை 2 வேளை கொடுக்க பாண்டு, பெரும்பாடு தீரும்<sup>14</sup>.
- 2.ஆவாரை நெய்: வேளை ஒன்றுக்கு 1 கரண்டி வீதம் சாப்பிட்டு வர சகலமேக நீரிழிவு, பெரும்பாடு தீரும்<sup>3</sup>.
- 3.தாதுபுஷ்டி லேகியம்: 1 வேளைக்கு தேற்றான் விரை பிரமாணம் உண்ண பெரும்பாடு, எரிகுன்மம் நீங்கும்<sup>3</sup>.
- 4.கதளிகந்த ரசாயனம்: கொட்டைப்பாக்களவு தினம் 2 வேளை சாப்பிட பெரும்பாடு, பிரமேகம் நீங்கும்<sup>15</sup>.
- 5.மஞ்சளாதி குழம்பு: பிரமியம், பெரும்பாடு தீரும்<sup>12</sup>.

## 12.சீனி<sup>4</sup>

வேறு பெயர்கள்: இக்கு, வேய்

பயன்படும் உறுப்பு: சர்க்கரை

சுவை: இனிப்பு, தன்மை: தட்பம் , பிரிவு: இனிப்பு

செய்கை: உள்ளழலாற்றி, அழுகலகற்றி

பொதுகுணம்:

அருந்து மருந்திற் கனுபான மாகப்  
பொருந்துமடல் வாந்திபித்தம் போக்கும்- அருந்தருசி  
நீக்கு மதிகபத்தை நீற்றுமகிழ்ச்சியுண்  
டாக்கு நறுஞ்சர்க்க ரை.

இது மருந்துகளுக்கு அனுபானமாயுள்ளது. வாந்தி, பித்தம், சுவையின்மை போக்கும்.

## **BOTANICAL ASPECT**

### **1. Benincasa hispida:<sup>5</sup>**

#### **Vernacular names:**

Sanskrit: Kushmandam, English: White Pumpkin, Hindi: Golkaddu, Telugu: Boodigummadi, Kannada: Kuvalau.

#### **Botanical classification:<sup>18</sup>**

Kingdom : Plantae  
Division : Magnoliophyta  
Class : Magnoliopsida  
Order : Violales  
Family : Cucurbitaceae  
Genus : Benincasa  
Species : Benincasa hispida

#### **Part used: <sup>5</sup>**

Fruit

#### **Botanical description:**

Fruits weigh about 3kg. The fruits are slightly long, spherical with light green flesh.

#### **Chemical constituents:**

The fruit contain lupeol, a sitosterol and their acetates, adenine, trigonelline, histidine. It also contains folate, niacin, pantothenic acid, pyridoxine, riboflavin, thiamine, vitamin C, A, E, K..

#### **Actions:**

Fruit is nutritive, styptic, diuretic, tonic, and also a valuable anti-mercurial.

## 2. Terminalia chebula<sup>19</sup>

### Vernacular names:

Sanskrit: Haritaki, English: Chebulik Myrobalan, Hindhi: Hara, Malayalam: Katukka, Telugu: Karitaki, Kannada: Harra.

### Botanical classification: <sup>18</sup>

Kingdom: Plantae  
Division : Magnoliophyta  
Class : Magnoliopsida  
Order : Myrtales  
Family : Combretaceae  
Genus : Terminalia  
Species : Terminalia chebula

### Part used: <sup>19</sup>

Fruit

### Botanical description:

Drupes ellipsoidal, obovoid or ovoid, yellow to orange- brown, sometimes tinged with red or black and hard when ripe, 3-5 cm long, 5 ribbed on drying.

### Physical constants:

Foreign matter- not more than 1%, total ash – not more than 5%, acid insoluble ash – not more than 5%, alcohol soluble extractive- not less than 40%, water soluble extractive – not less than 60%.

### Chemical constituents:

Tannic acid, vitamin C, anthraquinone glycoside, chebulic acid, chebulinic acid, chebulagic acid, terchebin, tetrachebulin, arachidic, behenic, linoleic, oleic, palmitic and stearic acids.

**Pharmacological activities:**

Astringent, Antimicrobial and Antispasmodic.

**Actions and uses:**

Fruits are astringent, antiseptic, and anti-inflammatory. They are useful in wounds, ulcers and haemorrhoids. Studies revealed that the herb is used as a laxative and it has haemostatic, diuretic and cardiogenic activities. Terminalia chebula has the ability to stop bleeding and prevent a medical condition called haemorrhage.

### **3. Terminalia bellirica<sup>19</sup>**

**Vernacular names:**

Sanskrit: Bibhitaka, English: Belliric Myrobalan, Hindi: Baheda, Malayalam: Tanni, Telugu: Tandra, Kannada: Behara.

**Botanical classification:<sup>18</sup>**

Kingdom: Plantae  
Division : Magnoliophyta  
Class : Magnoliopsida  
Order : Myrtales  
Family : Combretaceae  
Genus : Terminalia  
Species : Terminalia bellirica

**Part used:**

Fruit

**Botanical description:**

Fruits globular, 1.5-2.5 cm in diam., obscurely 5- angled when dry.

**Physical constants:**

Foreign matter- not more than 2%, total ash- not more than 7%, acid insoluble ash- not more than 1%, alcohol soluble extractive- not less than 8%, water soluble extractive- not less than 35%.

**Chemical constituents:**

Chebulagic acid, ellagic acid, gallic acid, fructose, galactose, mannitol, rhamnose, b-sitosterol, bellericanin.

**Pharmacological activities:**

Fruits are astringent, styptic, and anti-inflammatory.

**Actions and uses:**

They are useful in haemorrhages, ulcers and general debility.

#### **4. Zingiber officinale<sup>19</sup>**

**Vernacular names:**

Sanskrit: Shunthi, English: Ginger, Hindi: Adrak, Malayalam: Chukku, Telugu: Sonthi, Kannada: Alla

**Botanical classification:<sup>18</sup>**

Kingdom: Plantae  
Division : Magnoliophyta  
Class : Monocotyledon  
Order : Zingiberales  
Family : Zingiberaceae  
Genus : Zingiber  
Species : Zingiber officinale.

**Part used:**

Dried rhizome.



**Botanical description:**

Rhizome stout, tuberous with erect leafy stem, 60-90 cm tall.

**Physical constants:**

Total Ash: not more than 6%, water soluble ash: not less than 1.5%, alcohol soluble extractive: not less than 3%, water soluble extractive: not less than 10%.

**Chemical constituents:**

Gingerenone A and B, gingerols I, II and III, shagaols, zingiberene, gingerol, zingiberenol.

**Pharmacological activities:**

Anti-inflammatory, antioxidant, hepatoprotective, inhibition of prostoglandin release.

**Actions and uses:**

The dry ginger is stimulant and carminative. It is prescribed as an adjunct to many tonic and stimulating remedies.

Inhibition of prostaglandin and leukotriene formation could explain ginger traditional use as an anti-inflammatory agent, and anti-inflammatories are effective in reducing the heavy flow during menses.

## **5. Piper nigrum<sup>19</sup>**

**Vernacular names:**

Sanskrit: Maricha, English: Black Pepper, Hindi: Mirch, Malayalam: Kurumulaku, Telugu: Miriyalu, Kannada: Miri.

**Botanical classification:** <sup>18</sup>

Kingdom: Plantae

Division: Magnoliophyta

Class: Dicotyledon  
Order: Piperales  
Family: Piperaceae  
Genus: Piper  
Species: Piper nigrum

**Part used:**

Fruit.

**Botanical description:**

Fruits ovoid or globose, one seeded bright red when ripe.

**Physical constants:**

Total Ash – not more than 5%, acid insoluble ash- not more than 0.5%, alcohol soluble extractive- not less than 6%, water soluble extractive- not less than 6%.

**Chemical constituents:**

Piperine, piperonal, piperoleine A and B, piperide.

**Pharmacological activities:**

Antioxidant, analgesic and anti-inflammatory.

**Actions and uses:**

It is useful in haemorrhoids, eczema, vertigo and skin diseases.

## **6. Piper longum<sup>19</sup>**

**Vernacular names:**

Sanskrit: Pippali, English: Long Pepper, Hindi: Pipli, Malayalam: Tippali, Telugu: Pipallu, Kannada: Hipli.

**Botanical classification:<sup>18</sup>**

Kingdom : Plantae

Division : Magnoliophyta  
Class : Dicotyledon  
Order : Piperales  
Family : Piperaceae  
Genus : Piper  
Species : Piper longum

**Part used :**

Fruit

**Botanical description:**

Fruits ovoid, yellowish orange, sunk in fleshy spike.

**Chemical constituents:**

Piperlongumine, piperlonguminine, piperine, piperidine, pipernonaline and piperundecalidine.

**Pharmacological activities:**

Anti-Inflammatory, antispasmodic, and immunostimulatory.

**Uses:**

The fruits are used after child birth to check post partum hemorrhages, asthma and in diarrhea.

## **7. Glycyrrhiza glabra<sup>19</sup>**

**Vernacular names:**

Sanskrit: Yashtimadhu, English: Liquorice, Hindhi: Mulhatti, Malayalam: Yashtimadhukam, Telugu: Athimadhuramu, Kannada: Madhuka.

**Botanical classification:<sup>18</sup>**

Kingdom: Plantae  
Division: Magnoliophyta  
Class : Dicotyledon

Order : Fabales  
Family : Fabaceae  
Genus : Glycyrrhiza  
Species: Glycyrrhiza glabra

**Part used:**

Root

**Chemical constituents:**

Glycyrrhizine, quercetin, astragalin, kaempferol, liquiritigenin, asparagin, glycyrin, glabrene, glabranine, glycyrrhizic acid.

**Pharmacological activities:**

Smooth muscle depressant, hepatoprotective, anti-inflammatory and anti-oxidant.

**Actions and uses:**

The roots are sweet, haemostatic. It is useful in hemorrhoids, hemorrhage and meno-metrorrhagia.

## **8. Elettaria cardamomum<sup>19</sup>**

**Vernacular names:**

Sanskrit: Sukshmaila, English: Cardamom, Hindi: Choti Ilayachi, Malayalam: Elam, Telugu: Elakkayalu, Kannada: Elakki.

**Botanical classification:<sup>18</sup>**

Kingdom: Plantae  
Division: Magnoliophyta  
Class : Moncotyledon  
Order : Zingiberales  
Family: Zingibearaceae  
Genus : Elettaria  
Species: Elettaria cardamomum

**Part used:**

Seed

**Botanical description:**

Fruits trilocular, subglobose or fusiform to ovoid capsule. Seeds 15-20 per pod, brownish black, angled, rugose, and covered with a thin mucilaginous membrane.

**Physical constants:**

Total Ash- not more than 6%, acid insoluble ash- not more than 4%, alcohol soluble extractive: not less than 2%, water soluble extractive- not less than 10%, volatile oil- not less than 4%.

**Chemical constituents:**

A Pinene, sabinene, myrcene, limonene, cineol, cymene, camphene neryl acetate, geraniol.

**Pharmacological activities:**

Anti-inflammatory, antispasmodic, analgesic.

**Actions and uses:**

Seeds are cooling, stimulant, tonic. It is useful in hemorrhoids, burning sensation and debility.

## **9. Syzygium aromaticum<sup>19</sup>**

**Vernacular names:**

Sanskrit: Lavanga, English: Cloves, Hindi: Lavanga, Malayalam: Karampu, Telugu: Lavangalu, Kannada: Lavanga.

**Botanical classification:<sup>18</sup>**

Kingdom: Plantae

Division: Magnoliophyta

Class : Dicotyledon

Order : Myrtales  
Family : Myrtaceae  
Genus : Syzygium  
Species : Syzygium aromaticum  
**Part used:** Flower buds

**Botanical description:**

Flower buds greenish to pink, aromatic, clustered at the ends of branches.

**Physical constants:**

Foreign matter: not more than 2%, total ash: not more than 7%, acid insoluble ash: not more than 1%, alcohol soluble extractive: not less than 3%, water soluble extractive: not less than 9%, volatile oil- not less than 15%.

**Chemical constituents:**

Polyoxygenated chromone C-glucoside, isobiflorin, and biflorin. Eugenol acetate, eugenol, eugenine, eugenitine.

**Pharmacological activities:**

Antioxidant, anticonvulsant.

**Actions and uses:**

The cloves are acrid, bitter and appetizer. It is useful in general debility, burning sensation and neuralgia.

## **10. *Michelia champaca*<sup>19</sup>**

**Vernacular names:**

Sanskrit: Champaka, English: Golden Champa, Hindi: Champaka, Malayalam: Campakam, Telugu: Campangi, Kannada: Sampige.

**Botanical classification:**<sup>18</sup>

Kingdom: Plantae

Division: Magnoliophyta  
Class: Magnoliopsida  
Order: Magnoliales  
Family: Magnoliaceae  
Genus: Michelia  
Species: Michelia champaca  
Part used: Flowers

**Chemical constituents:**

Mono- and sesquiterpenes, b-sitosterol and its glucoside parthenolide, micheliolide, macheline A, ushinsunine, magnoflorine.

**Actions and uses:**

Flowers are bitter, astringent and haemostatic. It is useful in haemoptysis, burning sensation and dysmenorrhoea. Wound healing activity of Michelia champaca was in immuno suppressed rats.

## **11. Cuminum cyminum<sup>19</sup>**

**Vernacular names:**

Sanskrit: Krishnajeeraka, English: Common Caraway, Hindi: Kalajira, Malayalam: Karinjeerakam, Telugu: Nalla-Jeelakara, Kannada: Karijeerige.

**Botanical classification:<sup>18</sup>**

Kingdom: Plantae  
Division: Magnoliophyta  
Class : Dicotyledons  
Order : Apiales  
Family : Apiaceae  
Genus : Cuminum  
Species : Cuminum cyminum.

**Part used:**

Fruit

**Botanical description:**

Fruit a schizocarp, oblong-ovate; mericarps about 5mm long, linear oblong, curved, light to dark brown with 5 ribs.

**Physical constants:**

Foreign matter: not more than 2%, total ash- not more than 9%, acid insoluble ash- not more than 1.5%, alcohol soluble extractive: not less than 2%, water soluble extractive- not less than 12%, volatile oil- not less than 3.5%.

**Chemical constituents:**

P-cymene, cuminaldehyde, carvone, lipids, umbelliferone, scopoletin, herniarin, abscisic acid.

**Pharmacological activities:**

Antispasmodic, antiseptic.

**Actions and uses:**

Fruits are antiseptic, carminative, stimulant and tonic. It is useful in diarrhea, lumbago and rheumatism.

## **12. Saccharum officinarum<sup>19</sup>**

**Vernacular names:**

Sanskrit: Ikshu, English: Sugarcane, Hindi: Ikha, Malayalam: Karumbu, Telugu: Charki, Kannada: Kabbu.

**Botanical classification:<sup>18</sup>**

Kingdom: Plantae

Division: Magnoliophyta

Class : Dicotyledons



Order : Cyperales  
Family : Poaceae  
Genus : Saccharum  
Species : Saccharum officinarum

**Part used:**

Stem

**Physical constants:**

Foreign matter- not more than 2%, total ash- not more than 6%, acid insoluble ash- not more than 2.5%, alcohol soluble extractive- not less than 15%, water soluble extractive- not less than 17%.

**Chemical constituents:**

Sucrose, glucose, fructose, pectins, free acids, thiamine, riboflavin, niacin, pantothenic acid, vitamin D, hemicellulose, saccharetin, anthocyanins.

**Pharmacological activities:**

Antioxidant.

**Actions and uses:**

The stems are sweet, cooling haemostatic and tonic. It is useful in haematemesis, intrinsic hemorrhage and anemia.

## MINERALOGICAL ASPECT

### கல்மதம்

இது ஒரு உபரச சரக்காகும். வாயுபூத கூறாகும்.<sup>57</sup>

வேறு பெயர்கள்:<sup>21</sup>

- கல்தீட்டு
- கல்மலையினாதாம்
- மலைத்துடக்கு
- மலைத்தூமை
- செந்நீர்
- கல்காமி
- கல்லுக்குள்சோரம்
- மலையெத்தம்

கல்மத அடையாளம்:<sup>22</sup>

ஆச்சென்ற கல்மதத்தின் அடையா ளங்கேள்  
அதுங்காமல் கட்டியாகத் தான் இருக்கும்  
போச்சென்ற சதைப்போன்றும் சிவந்த ரேகை  
புகழாக மயிர்போல நீண்டு வீழும்  
வேச்சென்ற விளக்கதனில் வாட்டி னாக்கால்  
மேன்மையான அரக்குபோலே இளகிப் போகும்  
தோச்சியேதான் வெங்காரம் ரவியில் ஏழு  
தினம்போட வெங்காரம் கட்டிப் போமே.

கல்மதம் வெண்மையாகவும், வழுவுழுப்பாகவும், மாவுக்கல்லைப் போன்று காணப்படும். இதில் புகாரச் சத்து மிகுந்து காணப்படும்.<sup>20</sup>

செய்கை: சமனகாரி, சிறுநீர்பெருக்கி<sup>20</sup>

**குணம்:**

கண்ட பிணிமேகங் கல்லொடுநீ ஞுனடைப்பு  
வண்டற் கிரிச்சரநோய் மாபிரமி- யுண்டலினாற்  
பன்மதஞ்சேர் தாதுநட்டம் பன்னுமிந்நோய்க் கூட்டத்துட்  
கன்மதஞ்சேர் ரச்சரக்குக் காண்.<sup>20</sup>

கல்மதம் மேகத்தைச் சார்ந்த பல மூத்திரரோகங்களையும், கல்லடைப்பு, சதையடைப்பு, வாதப் பிரமியம் நீக்கும்.

**கல்மத சுத்தி முறைகள்:**

- 1.பசுநீரில் ஊறவைத்துக் கழுவி எடுத்துக் கொள்ள சுத்தியாகும்.<sup>23</sup>
- 2.செங்கழுநீர் கிழங்குச் சாற்றில் 2 நாள் ஊறவைத்தெடுக்க சுத்தியாகும்.<sup>6</sup>
- 3.கல்மதத்தைச் சிறு துண்டுகளாகச் செய்து நல்லெண்ணெய்யில் ஒரு வாரம் ஊறவைத்தெடுத்து கழுவி எடுத்துக் கொள்ள சுத்தியாகும்.<sup>7</sup>
- 4.பசுவின் பாலில் எட்டு நாட்கள் ஊறவைத்தெடுத்து கழுவி எடுத்துக் கொள்ள சுத்தியாகும்.<sup>7</sup>

**கல்மதம் சேரும் பிற மருந்துகள்:**

1. கல்மதப் பற்பம்: 1-8 குன்றி எடை சாப்பிட ரத்தங்கக்கல், ரத்தவாந்தி தீரும்.<sup>20</sup>
2. புஷ்பானுகச் சூரணம்: 2-5 வராகன் தேனில் உண்ண சுபாவமாக ஏற்படும் இரத்தஓழுக்கு மிகுதியாக ஏற்படின் வரும் வியாதிகள் நீங்கும்.<sup>17</sup>
3. நந்தி மெழுகு: 200-500 மி.கி பனைவெல்லத்தில் உண்ண இளைப்பு, படர்தாமரை தீரும்.<sup>8</sup>

## **KALMADHAM (ROCK ALUM)**

It is one of the 120 kinds of natural substances contemplated in Tamil Medical sciences. This drug when burnt and examined is found to contain potassium, calcium, magnesium, silica, etc.

The analysis of the drug shows the presence of following elements:

- 1.Magnesium
- 2.Iron
- 3.Silica
- 4.Calcium
- 5.Phosphorous
- 6.Aluminium
- 7.Chlorine
- 8.Sulphur
- 9.Potassium

## **Physical Properties of Kuzhpaanda Chooranam**

The Physical properties of Kuzhpaanda Chooranam were analysed in the following procedure. It was done at Sri Ramachandra University, Chennai.

### **Materials and Methods:**

#### **pH at 10% of aqueous solution:**

Five grams of Kuzhpaanda Chooranam was weighed accurately and placed in clear 100 ml beaker. Then 50 ml of distilled water was added to it and dissolved well. After 30 minutes it was then applied in to pH meter at standard buffer solution of 4.0, 7.0, and 9.2.

#### **Ash Values**

The Ash values are a measure of the inorganic constituents present in the raw drug. High ash content explains its unsuitable nature to be used as a drug

#### **Total Ash**

A little of extract was taken in a silica crucible previously ignited, cooled and weighed. It was incinerated by gradually increasing the heat not exceeding dull red heat (450°C) until free from carbon, cooled and weighed. The percentage of ash was calculated with reference to air- dried drug. The procedure was repeated to get the constant weight.

#### **Water soluble ash**

The total ash was boiled with 25 ml water and filtered through ash less filter paper (Whatmann 4.1). It was followed by washing with hot water. The filter paper was dried and ignited in the silica crucible, cooled and the water insoluble ash was weighed. The water-soluble ash can be calculated by subtracting the water insoluble ash from the total ash.

#### **Acid insoluble ash**

The total ash obtained was boiled for 5 minutes with 25 ml of (10% w/v) dilute hydrochloric acid and filtering through ash less filter paper (Whatmann 4.1). The filter paper was ignited in the silica crucible, cooled and insoluble ash was weighed. (Refer Annexure Table 1.)

# **HIGH PERFORMANCE THIN LAYER CHROMATOGRAPHY (HPTLC)**

HPTLC of Kuzhpaanda Chooranam was done at SriRamachandra University, Chennai.

## **HPTLC Fingerprint - RH1**

### **Sample Preparation**

100 mg of extract was weighed and dissolved in 70% methanol to get a concentration of 10mg/ml concentration this is then used for injection.

### **CHROMATOGRAPHIC CONDITION FOR HPTLC FINGER PRINT**

SampleName	:	Kuzhpaanda Chooranam
Sample-ID	:	106
Stationary phase	:	Silica gel F 254
Mobile phase	:	n-Hexane: Ethyl acetate: Formic acid 60:40:2.5 ml)
Scanning wavelength	:	254,298,489 nm
Sample concentration	:	20 mg/ml
Injecting volume	:	5, 10 $\mu$ l
Development mode	:	Ascending mode

### **Significance of HPTLC fingerprinting in Standardisation**

Standardisation of traditional medicine has become mandatory in the present national and international scientific scenario, as they have to stand competing with stringent regulatory methods and also clinically. HPTLC is one of the versatile chromatographic methods presently available for the rapid analysis of herbal drugs due to several reasons. Firstly the time required for the demonstration of the most of the characteristic constituents of a drug is very quick and short. Secondly, in addition to qualitative detection, HPTLC also provides semi-quantitative information on the major active constituents of a drug, thus enabling an assessment of drug quality. Thirdly the fingerprint obtained is suitable for monitoring the identity and purity of drugs and for detecting adulteration and substitution. Hence in order to check the identity, purity and

standardise the quantity of active principles in the herbal extracts a HPTLC fingerprint of all the 12 ingredient medicinal plants used in the formulation has been obtained.

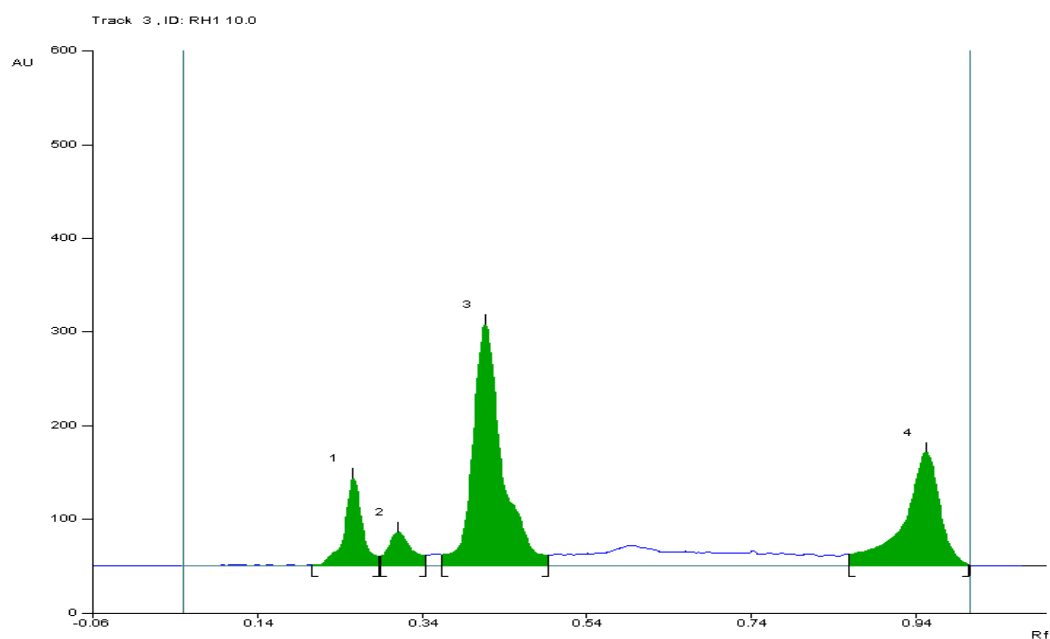
The distribution of phyto-constituents in a plant depends on various factors such as soil, time of collection period of storage, etc. So, it is necessary to standardize the extract being used for pharmacological studies. HPTLC serves as a convenient tool for finding out the distribution pattern of phyto constituents which is unique to each plant. The HPTLC finger-printing profile establishes the identity and purity of the raw drug being used. It helps in the authentication of the plant material.

### **Chromatographic Conditions**

The finger printing has been done using the following chromatographic conditions. Chromatography was performed on a 10x10 cm pre activated HPTLC silica gel 60F 254 plate. Samples were applied to the plate as 6mm wide band with an automatic TLC applicator Linomat 5 with N2 flow (CAMAG, Switzerland), 8mm from the bottom. Densitometric scanning was performed on CAMAG scanner III. The plates were pre-washed by methanol and activated at 60<sup>0</sup> C for 5 minutes prior to chromatography. The slit dimension was kept at 5 minutes x 0.45 minutes and 20 minutes scanning speed was employed. The mobile phase was chosen after running each plant in different mobile phases of varying polarity (Toluene, Toluene: Ethyl acetate and Ethyl acetate: Methanol) and 10 ml of mobile phase was used per chromatography. Linear ascending development was carried out in 20 cm x 10-cm twin glass chamber saturated with the mobile phase.

### **Chromatographic Analysis**

The hydro alcoholic extracts of the plants have been prepared at a concentration of 10 mg/10 ml in alcohol and were spotted using CAMAG Linomat 5 applicator. The method was optimized by selecting appropriate mobile phase for respective plant extracts and developed in a twin trough chamber, 20 x 10 cm at 25°C. The plates were dried by hair dryer. The developed plates were scanned at appropriate wavelength using CAMAG TLC scanner 3 and photo-documented using CAMAG REPROSTAR 3.



### INFERENCE:

HPTLC fingerprint of RH -1 shows four peaks at Rf values 0.25, 0.31, 0.41 & 0.95. The peak correspond to the Rf value 0.31 has maximum peak area of 7256.5. At this stage it is difficult to confirm the individual components present in the extract, but from our lab experience on phytochemical analysis, we suggest that the major peaks found in the fingerprint may be acidic glycosides / resins. Since, in the present chromatographic conditions, the above mentioned components will be eluted easy.

(Refer Annexure Fig. 106-1 to 106-16).



## BIO -CHEMICAL ANALYSIS OF KUZHPAANDA CHOORANAM

The biochemical analysis of the Kuzhpaanda Chooranam was carried out in the Biochemistry lab, National Institute of Siddha, Chennai.

S.No	EXPERIMENT	OBSERVATION	INFERENCE
1.	Appearance of sample	Sandal colour	
2.	<b>Solubility:</b> a. A small amount of the sample was shaken well with distilled water. b. A small amount of the sample was shaken well with con. HCl/Con. H <sub>2</sub> SO <sub>4</sub>	Sparingly soluble	Absence of Silicate
3.	<b>Action of Heat:</b> A small amount of the sample was taken in a dry test tube and heated gently at first and then strong.	No white fumes evolved	Absence of Carbonate
4.	<b>Flame Test:</b> A small amount (500mg) of the sample was made into a paste with con. HCl in a watch glass and introduced into non-luminous part of the Bunsen flame.	No Bluish green flame appeared.	Absence of Copper
5.	<b>Ash Test:</b> A filter paper was soaked into a mixture of sample and dil.cobalt nitrate solution and introduced into the Bunsen flame and ignited.	Yellow colour flame not appeared.	Absence of sodium

### Preparation of Extract:

5gm of Kuzhpaanda Chooranam was weighed accurately and placed in a 250ml clean beaker 50ml of distilled water is added. Then it was boiled well for about 10 minutes. Then it was cooled and filtered in a 100ml volumetric flask and made up to 100ml with distilled water.

S.No	EXPERIMENT	OBSERVATION	INFERENCE
	<b>I. Test For Acid Radicals</b>		
1.	<b>Test For Sulphate:</b> a. 2ml of the above prepared extract was taken in a test tube. To 2ml of 4% dil ammonium oxalate solution was added. b. 2ml of the above prepared extract was added with 2ml of dil-HCl until the effervescence ceases off. Then 2ml of dil.Barium chloride solution was added.	No Cloudy appearance	Absence of Sulphate
2.	<b>Test For Chloride:</b> 2ml of the above prepared extract was added with dil. HCl till the effervescence ceases. Then 2ml of dil.silver nitrate solution was added.	No cloudy appearance	Absence of Chloride
3.	<b>Test For Phosphate:</b> 2ml of the extract was treated with 2ml of dil.ammonium molybdate solution and 2ml of con.HNO <sub>3</sub> .	Yellow appearance absence	Absence of Phosphate
4.	<b>Test For Carbonate:</b> 2ml of the extract was treated with 2ml dil. Magnesium sulphate solution	No Cloudy appearance.	Absence of carbonate
5.	<b>Test For Nitrate:</b> 1gm of the substance was heated with copper turning and concentrated H <sub>2</sub> SO <sub>4</sub> and viewed the test tube vertically down.	No Brown gas evolved.	Absence of Nitrate
6.	<b>Test For Sulphide:</b> 1gm of the substance was treated with 2ml of con. HCL	No Rotten Egg Smelling gas.	Absence of Sulphide
7.	<b>Test For Fluoride &amp; Oxalate:</b> 2ml of extract was added with 2ml of dil. Acetic acid and 2ml dil.calcium chloride solution and heated.	No Cloudy appearance	Absence of fluoride and oxalate
8.	<b>Test For Nitrite:</b> 3 drops of the extract	No Characteristic	Absence of

	was placed on a filter paper, on that-2 drops of dil.acetic acid and 2 drops of dil.Benzidine solution was added.	changes	Nitrite
9.	<b>Test For Borate:</b> 2 Pinch (50mg) of the substance was made into paste by using dil.sulphuric acid and alcohol (95%) and introduced into the blue flame.	No Bluish green colour flame.	Absence of borate
	<b>II. Test For Basic Radicals</b>		
1.	<b>Test For Lead:</b> 2ml of the extract was added with 2ml of dil.potassium iodine solution.	No yellow Precipitate obtained.	Absence of Lead
2.	<b>Test For Copper:</b> One pinch (50mg) of substance was made into paste with con. HCl in a watch glass and introduced into the non-luminous part of the flame.	No Blue colour flame No Blue colour precipitate formed.	Absence of copper
3.	<b>Test For Aluminium:</b> To the 2ml of extract, dil.sodium hydroxide was added in 5 drops to excess.	Yellow colour appeared.	Presence of aluminium
4.	<b>Test For Iron:</b> a. To the 2ml of extract, 2ml of dil.ammonium solution was added. b. To the 2ml of extract 2ml thiocyanate solution and 2ml of conc. HNO <sub>3</sub> was added	Blood red colour appeared.	Presence of Iron
5.	<b>Test For Zinc:</b> To 2ml of the extract, dil.sodium hydroxide solution was added in 5 drops to excess and dil.ammonium chloride was added.	White precipitate was not formed	Absence of Zinc
6.	<b>Test For Calcium:</b> 2ml of the extract was added with 2ml of 4% dil.ammonium oxalate solution	Cloudy appearance and white precipitate was obtained	Presence of calcium

7.	<b>Test For Magnesium:</b> To 2ml of extract dil.sodium hydroxide solution was added in drops to excess.	White precipitate was obtained	Presence of Magnesium
8.	<b>Test For Ammonium:</b> To 2ml of extract 1 ml of Nessler's reagent and excess of dil.sodium hydroxide solution are added.	No Brown colour appeared	Absence of ammonium
9.	<b>Test For Potassium:</b> A pinch (25mg) of substance was treated of with 2ml of dil.sodium nitrite solution and then treated with 2ml of dil.cobalt nitrate in 30% dil.glacial acetic acid.	No Yellowish precipitate was obtained.	Absence of Potassium
10.	<b>Test For Sodium:</b> 2 pinches (50mg) of the substance was made into paste by using HCl and introduced into the blue flame of Bunsen burner.	Yellow colour flame not appeared	Absence of Sodium
11.	<b>Test For Mercury:</b> 2ml of the extract was treated with 2ml of dil.sodium hydroxide solution.	No yellow precipitate was obtained	Absence of mercury
12.	<b>Test For Arsenic:</b> 2ml of the extract was treated with 2ml of dil.sodium hydroxide solution.	No brownish red precipitate was obtained	Absence of arsenic
	<b>III. Miscellaneous</b>		
1.	<b>Test For Starch:</b> 2ml of extract was treated with weak dil.iodine solution	Blue colour developed	Presence of starch
2.	<b>Test For Reducing Sugar:</b> 5ml of Benedict's qualitative solution was taken in a test tube and allowed to boil for 2 minutes and added 8 to 10 drops of the extract and again boil it for 2 minutes. The colour changes are noted.	Brick red colour developed	Presence of reducing sugar
3.	<b>Test For The Alkaloids:</b> a) 2ml of the extract was treated with 2ml of dil.potassium iodide solution.	Yellow colour developed	Presence of Alkaloid

	b) 2ml of the extract was treated with 2ml of dil.picric acid. c) 2ml of the extract was treated with 2ml of dil.phosphotungstic acid.		
4.	<b>Test For Tannic Acid:</b> 2ml of extract was treated with 2ml of dil.ferric chloride solution	Black precipitate was obtained	Presence of Tannic acid
5.	<b>Test For Unsaturated Compound:</b> To the 2ml of extract 2ml of dil.Potassium permanganate solution was added.	Potassium permanganate was not decolorized	Absence of unsaturated compound
6.	<b>Test For Amino Acid:</b> 2 drops of the extract was placed on a filter paper and dried well. 20ml of Biurette reagent was added.	Violet colour not developed	Absence of amino acids
7.	<b>Test For Type Of Compound:</b> 2ml of the extract was treated with 2 ml of dil.ferric chloride solution.	No green colour developed  No red colour developed  No violet colour developed  No blue colour developed	Absence of oxyquinole pinephrine and pyrocatechol  Anti pyrine, Aliphatic amino acids and meconic acid are absent  Apomorphine salicylate and Resorcinol are absent  Morphine, Phenol cresol and hydroquinone are absent

(Refer Annexure Table 2.)

## **Atomic Absorption Spectrophotometer (AAS)**

AAS of Kuzhpaanda chooranam was done at Sri Ramachandra University, Chennai.

### **Elemental Analysis using Atomic Absorption Spectrophotometer**

In this method the sample, in the form of a homogeneous liquid, is introduced into a flame where thermal and chemical reactions create “free” atoms capable of absorbing, emitting or fluorescing at characteristic wavelengths.

In Atomic Absorption Spectrophotometer (AAS) the majority of free atoms in the commonly used flames were in the ground state, but that the flames did not also have enough energy to excite these atoms. A light source emitting a narrow spectral line of the characteristic energy is used to excite the free atoms formed in the flame. The decrease in energy (absorption) is then measured.

## **METHODOLOGY**

### **I. Microwave Digestion For Elemental Analysis (Model Name: Multiwave3000)**

#### **Digestion Procedure:**

200mg of the given sample is placed in a digestion vessel, acid is added and the mixture is heated for several minutes. After the digestion, the samples are diluted to a specific volume. If too much sample is used in wet digestion, the reaction mixture can become violent. The samples are placed in digestion vessels that fit directly into digestion racks. There are several different acids or mixtures of acids used for digestion, the most common of which is concentrated Hydrochloric acid. The samples are heated slowly at a high temperature. After digestion, the samples are diluted to the appropriate volume with deionized H<sub>2</sub>O.

### **II. Elemental Analysis using Atomic Absorption Spectrophotometer**

The elemental analysis of digested samples have been determined by Atomic Absorption Spectrophotometer- Flame technique (AAS model 400 Perkin Elmer). Working standard solutions of Fe and Mg were prepared from stock standard solution of 1000 ppm from MERCK. Using blank solution to zero the instrument performs the

Calibration. The standards are then analyzed and their absorbance recorded. A graph of Absorbance Vs Concentration is plotted. Calibration of the instrument was repeated periodically during operation. A blank reading was also taken and necessary correction was made during the calculation of concentration of various elements.

The digested material was made upto 100 ml for analysis in an (AAS) atomic absorption spectrophotometer (Perkin Elmer). The results were calibrated using standard calibration curve. (Refer Annexure Table 3).

#### **Instrumental conditions for elemental analysis**

<b>Element</b>	<b>Wavelength nm</b>	<b>Light source</b>	<b>Flame type</b>
<b>Magnesium</b>	<b>285.2</b>	<b>HCL</b>	<b>Air/Ac</b>
<b>Iron</b>	<b>386.0</b>	<b>HCL</b>	<b>Air/Ac</b>

**Air/Ac: Air-Acetylene; HCL: Hallow cathode lamp**

**A - Ac:** Air-Acetylene; **HCL:** Hallow cathode lamp; **EDL:** Electrode less discharge lamp

# TOXICITY STUDIES OF KUZHPAANDA CHOORANAM

## MATERIALS AND METHODS

### Animals:

Mice of either sex weighing 25-30g and rats weighing 210-240gms were obtained from the animal house of Vels University. The animals were used with the approval of the Institute animal ethics committee and obtained from Vels University, Chennai. They were fed with a balanced standard pellet diet and maintained under standard laboratory conditions, providing 24-28<sup>0</sup>C temperature, standard light cycle (12 h light, 12 h dark) and water ad libitum. Animals were kept in cages with raised floors of wide mesh to prevent coprophagy. Animal welfare guidelines were observed during the maintenance period and experimentation. The rats were randomly assigned to control and different treatment groups, six animals per group. (Registration no. - XIII/VELS/PCOL/41/2000/CPCSEA/IAEC/08.08.2012). The animals were acclimatized for one week under laboratory conditions.

### ACUTE TOXICITY STUDY:

Acute oral toxicity test for the Kuzhpaanda Chooranam was carried out as per OECD Guidelines 425. As with other sequential test designs, care was taken to ensure that animals are available in the appropriate size and age range for the entire study. The test substance was administered in a single dose by gavage using a stomach tube or a suitable intubation cannula. The fasted body weight of each animal is determined and the dose was calculated according to the body weight. After the substance has been administered, food was withheld for a further 2 hours in mice. Single animals were dosed in sequence usually at 48 h intervals.

However, the time interval between dosing was determined by the onset, duration, and severity of toxic signs. Treatment of an animal at the next dose was delayed until one is confident of survival of the previously dosed animal.

**Observation of toxicity signs:** General behavior, respiratory pattern, cardiovascular signs, motor activities, reflexes, change in skin and fur, mortality and the body weight



changes were monitored daily. The time of onset, intensity, and duration of these signs, if any, was recorded.

The time interval was adjusted as appropriately in case of inconclusive response. The test is simpler to implement when a single time interval was used for making sequential dosing decisions. Special attention was given during the first 4 hours and daily thereafter, for a total of 14 days, except where they need to be removed from the study and humanely killed for animal welfare reasons or are found dead.

All observations were systematically recorded and observations include changes in skin and fur, eyes and mucous membranes, and also respiratory, circulatory, autonomic and central nervous systems, and somatomotor activity and behaviour pattern. Attention was directed to observations of tremors, convulsions, salivation, diarrhea, lethargy, sleep and coma. The principles and criteria summarized in the Humane Endpoints Guidance Document taken into consideration. Animals found in a moribund condition and animals showing severe pain or enduring signs of severe distress was humanely killed. When animals are killed for humane reasons or found dead, the time of death was recorded.

## **SUB-ACUTE TOXICITY**

In a 28-days sub acute toxicity study, twenty four rats of either sex were divided into four groups of 6 rats each. Group I that served as normal control was administered with distilled water (p.o.) while groups II, III and IV were administered daily with the Kuzhpaanda Chooranam (p.o.) for 28 days at a dose of 100, 200 and 400 mg/kg respectively. The animals were then observed daily for gross behavioural changes and any other signs of subacute toxicity.

The weight of each rat was recorded on day 0 and weekly throughout the course of the study, food and water consumption per rat was calculated. At the end of the 28 days they were fasted overnight, each animal was anaesthetized with diethylether, following which they were then dissected and blood samples were obtained by cardiac puncture into heparinised tubes. The blood sample collected from each rat was centrifuged with 3000 X g at 4°C for 10 min to separate the serum and used for the biochemical assays.

**Hematological and blood biochemical analysis:**

At the end of the study, all animals were kept fasted for 16-18 h and then anesthetized with anesthetic ether on the 28th day. Blood samples for hematological and blood chemical analyses were taken from retro orbital vein. Heparinized blood samples were taken for determining complete blood count (white blood cell count, differential white blood cell count, platelet count, red blood cell count, hematocrit, and hemoglobin) by semiautomated hematology analyzer.

The serum from non-heparinized blood was carefully collected for blood chemistry and enzyme analysis like glucose, creatinine, total protein, albumin, total and direct bilirubins, Serum glutamate-oxaloacetate transaminase (SGOT), Serum glutamate pyruvate transaminase (SGPT), and Alkaline phosphatase (ALP) were automatically determined using autoanalyzer.

**Necropsy:**

All rats were sacrificed after the blood collection. The positions, shapes, sizes and colors of internal organs were evaluated. The Spleen, Testes, Pancreas, Lung, Liver, Brain, Heart, Stomach, Intestine, Bone, Ovary, and Kidney tissues were excised from all rats to visually detect gross lesions, and weighed to determine relative organs' weights and preserved in 10% neutral formalin for histopathological assessment. The tissues were embedded in paraffin and then sectioned, stained with haematoxylin and eosin and were examined microscopically.

**Statistical analysis**

Values were represented as mean  $\pm$  SEM. Data were analysed using one-way analysis of variance (ANOVA) and group means were compared using the Tukey-Kramer Multiple Comparison test using Instat-V3 software. P values < 0.05 were considered significant.

**RESULTS:**

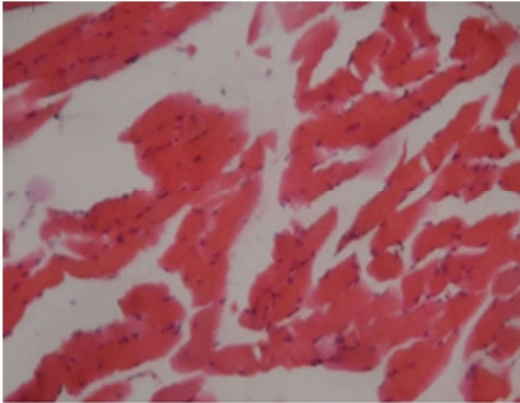
The acute toxicity results revealed that the kuzhpaanda chooranam is tolerable upto 2000mg/kg in mice and 1/10<sup>th</sup> of the maximum tolerable dose was considered as therapeutic dose (200mg/kg). Animals were not shown any significant toxic clinical signs during the dosing period of 28 days. All animals from control and all the treated dose

groups survived throughout the dosing period of 28 days. Results of body weight determination of animals of control and different dose groups exhibited comparable body weight gain throughout the dosing period of 28 days. During dosing period, the quantity of food consumed by animals from different dose groups was found to be comparable and normal with that of control animals. Ophthalmoscopic examination of animals in control and test product– treated groups did not reveal any major and remarkable abnormality. These tests conducted on the experimental animals at termination and recorded did not reveal any abnormalities. Urine analysis data of control group and treated group of animals determined in week 4 did not reveal any abnormalities. Mean Relative Organ Weights are found to be comparable and normal. Gross pathological examination of animals in control as well as the treated groups did not reveal any abnormalities. The results of haematological investigations revealed no major changes in the values of different parameters investigated when compared with control; however, the increase or decrease in the values obtained was within normal biological and laboratory limits. Results of Biochemical investigations revealed normal.

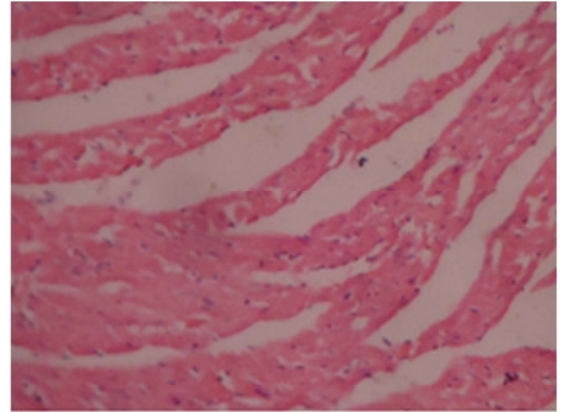
#### **CONCLUSION:**

Based on these findings, no toxic effect was observed upto 400mg/kg of *Kuzhpaanda Chooranam* treated via oral route over a period of 28 days. So, it can be concluded that the *Kuzhpaanda Chooranam* can be prescribed for therapeutic use in human with the dosage recommendations of upto 400mg/kg body weight p.o(Refer Annexure Table 5 to Table 13)

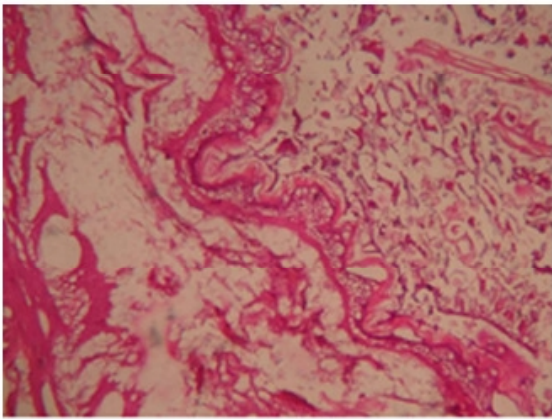
## HISTOPATHOLOGICAL SLIDES



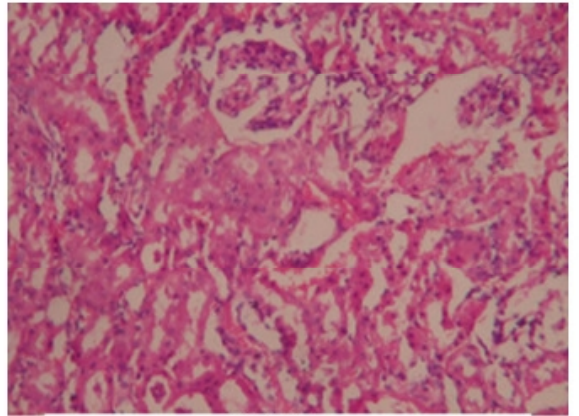
BONE



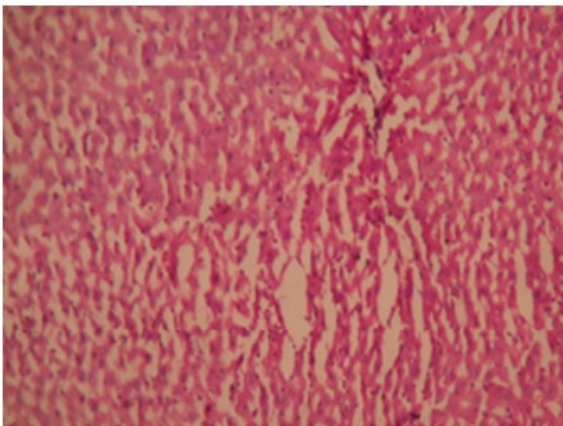
HEART



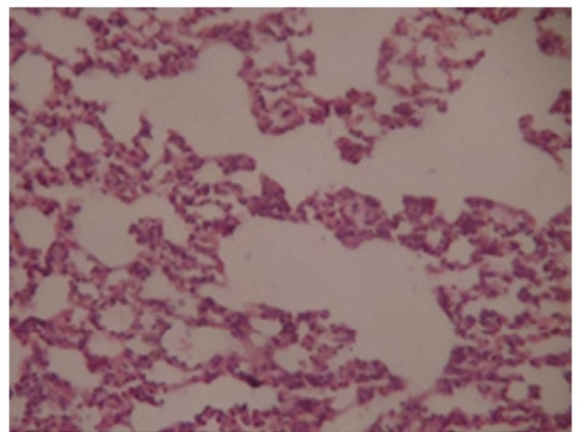
INTESTINE



KIDNEY

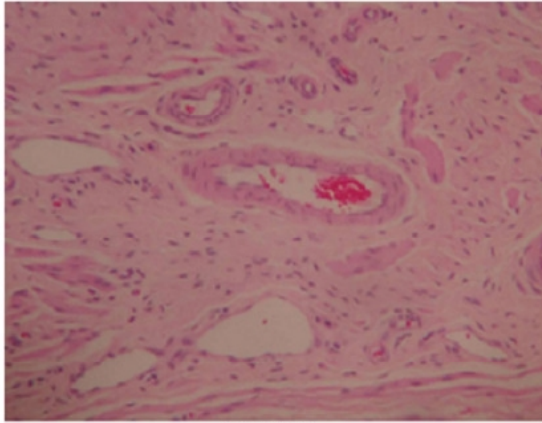


LIVER

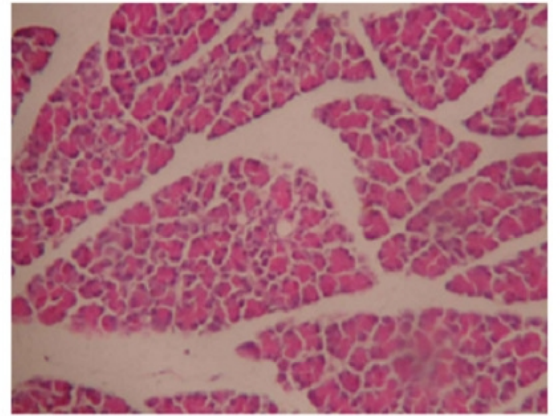


LUNG

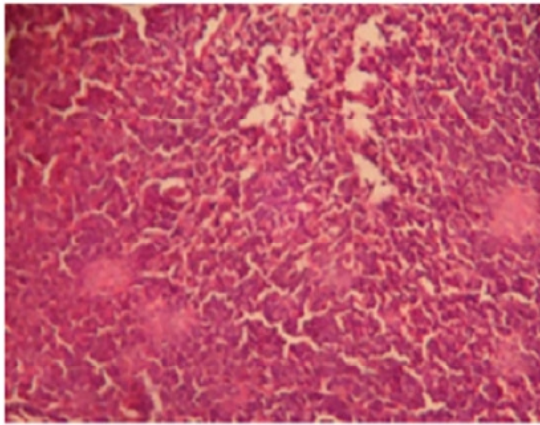




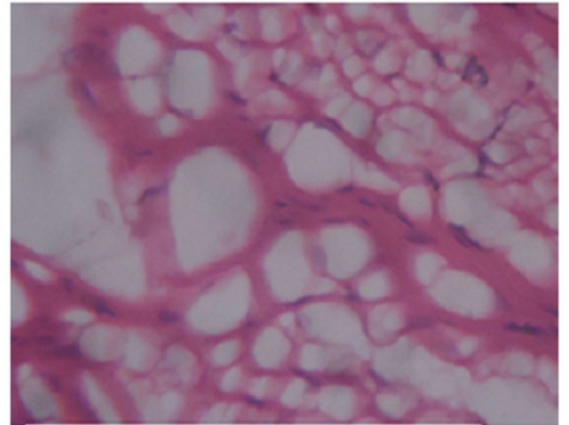
Ovary



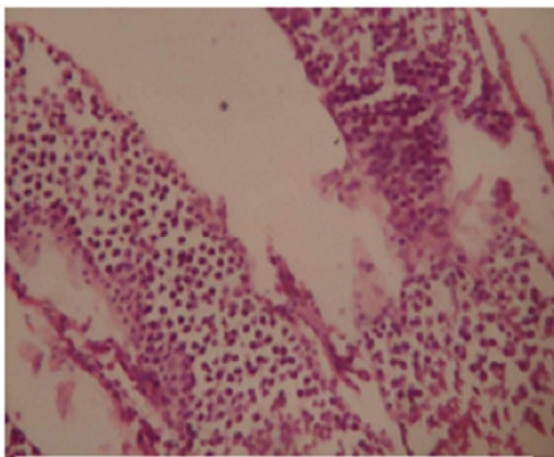
Pancreas



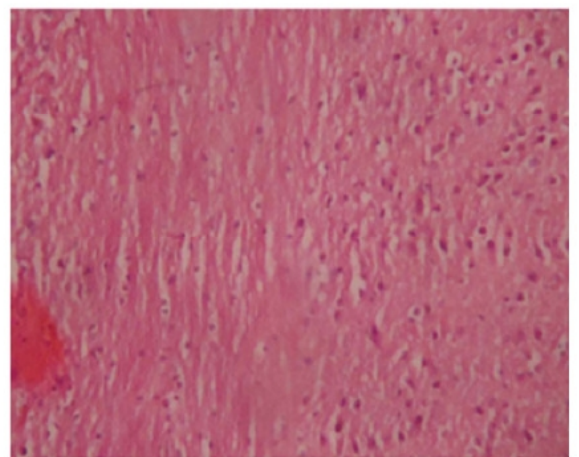
Spleen



Stomach



Testis



Brain

## PHARMACOLOGICAL STUDY<sup>24</sup>

### STYPTIC ACTIVITY OF KUZHPAANDA CHOORANAM

#### Stock Solution Preparation:

The test drug 200mg of fine powder form of Kuzhpaanda Chooranam was accurately weighed using electronic balance and mixed thoroughly with 10ml of 2% Carboxy Methyl Cellulose (CMC) solution to achieve 20mg/ml stock solution and this was used for further study.

#### Drug Treatment:

Over night fasted mice were divided into 3 groups of six mice each. Group I served as a control, received vehicle 2% CMC only orally for three days. Group II received Kuzhpaanda Chooranam at the dose level of 200mg/kg orally for three days and also administered (25 $\mu$ l of 50mg/ml stock suspension) on open liver wound at the time of bleeding and Group III was untreated normal animals.

#### Induction of Experimental Bleeding

After last dosing of Kuzhpaanda Chooranam suspension oral administration and 30 minutes of absorption period, the animals were placed on the dissection board and the animals were anesthetized using anesthetic ether. The abdomen of the animals was cut opened carefully without any damage to the major blood vessels under ether anesthesia, the left lobe of liver was located in the abdominal cavity and the tip is wounded carefully by making an incision to induce bleeding. Simultaneously the timer was switched on and the blood traces were fixed on the blotting paper at different time intervals in room temperature (27 $\pm$ 2<sup>0</sup>C). The time at which the bleeding ceased from the liver lobe was noted.

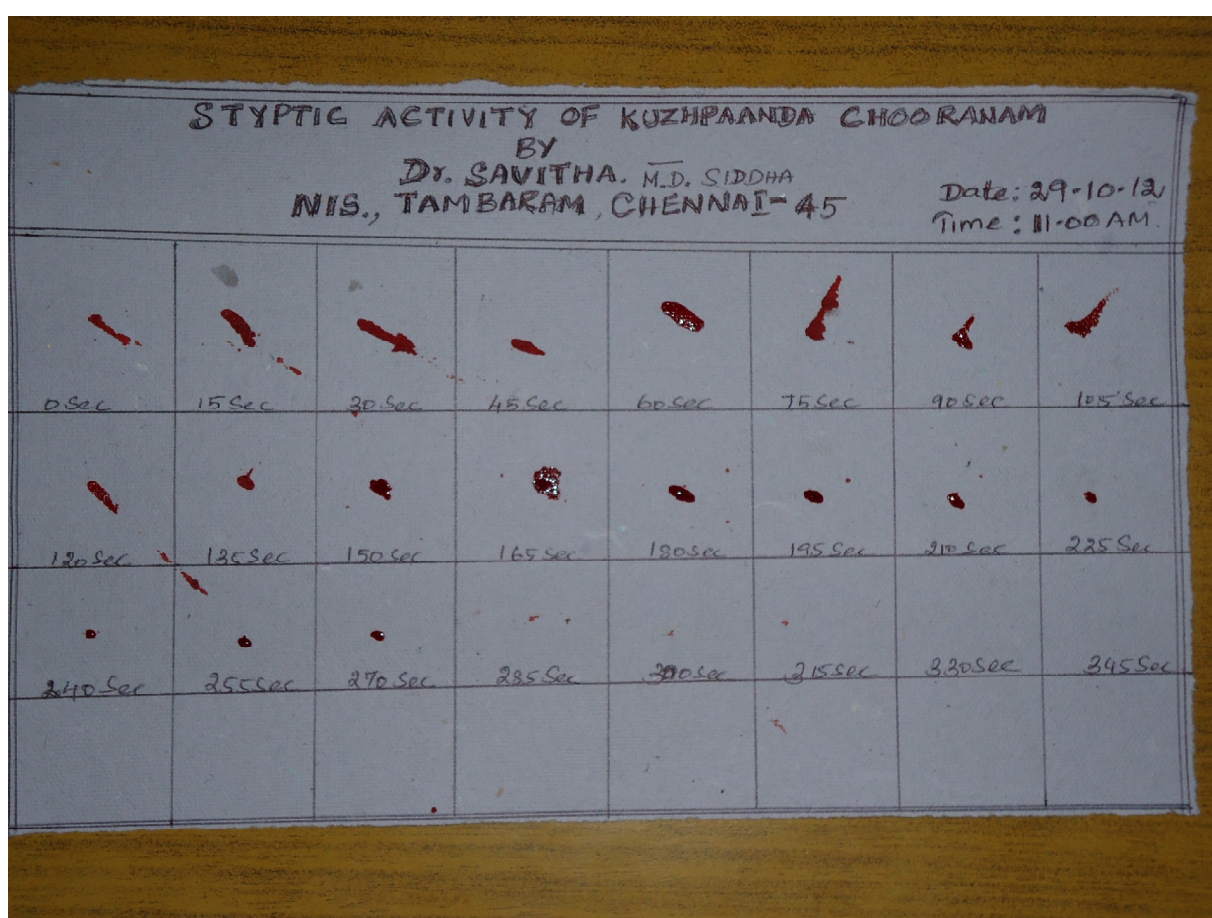
#### Statistical Analysis

The results were expressed as means  $\pm$  S.E.M. Data was analyzed by using one-way ANOVA followed by Dunnet test. P values of <0.05 was considered as significant.

## RESULTS AND DISCUSSION

In the present study, Group II received Kuzhpaanda Chooranam at the dose of 200mg/kg. p.o., for three days exhibited significant ( $P<0.01$ ) reduction in the duration of bleeding from the incised liver mechanical wound when compared to untreated normal and control animals. In conclusion, this study suggests that the Kuzhpaanda Chooranam is producing dose dependent styptic action and it can be clinically used as an Anti hemorrhagic agent after studying the systematic toxicity profile.

### STYPTIC ACTIVITY OF KUZHPAANDA CHOORANAM



(Refer Annexure Fig.1 and Table 4)

## பெரும்பாடு<sup>25</sup>

பூப்பு காலங்களில் குருதிக்கசிவு அதிகரித்துக் காணுவதைப் பெரும்பாடு என்பர். பூப்பு இடைக்காலம் சரியாகவும், பூப்பு கசிவு சதாரண அளவைவிட பெரிதும் அதிகரித்து பூப்புக்காலங்களில் காணுவதைப் பெரும்பாடு என்று கூறுவது மரபு.

பூப்பு இடைக்காலம் குறைந்தும் பூப்புக்காலம் சரியாகவுமிருந்தும் அல்லது பூப்பு இடைக்காலம் அதிகரித்தும் பூப்புக்காலம் சரியாகவுமிருந்தும் பூப்புக் கசிவு அதிகரித்திருந்தால் அதனை அபரிமிதப் பூப்பு என்பர்.

பூப்புக் காலங்களில்லாமல் சுயேச்சையாகப் பூப்பு இடைக்காலங்களில் குருதிக் கசிவு ஏற்பட்டால் அதைப் பெரும்பாடு எனப்படும்.

### பெரும்பாடு இருவகைப்படும்.

- 1.சாதாரணப் பெரும்பாடு
- 2.அசாதாரணப் பெரும்பாடு

### நோய் வரும் வழிகள்:

- 1.கருப்பையில் கழலை, கட்டிகள் வளருதல்.
- 2.சினைப்பை தாபிதம்
- 3.சினைப்பாதை தாபிதம்
- 4.குறைவீதன சத்து நோய்
- 5.உள்ளிடைச் சுரப்பிகளின் கோளாறு நோய்கள்.
- 6.பூப்பு முடிவு காலங்களில்
- 7.மனோவேகங்கள்
- 8.ஆரம்ப நிலைப் புற்று நோய்
- 9.உள்கவச சயநோய்
- 10.குறைக்கருச்சிதைவில் ஏற்பட்ட பின் தங்கிய செத்தைகள்.



யூகிமுனி அடியொற்றி இனி பெரும்பாட்டின் வகைகளைக் காண்போம்:

- 1.வாதப் பெரும்பாடு
- 2.பித்தப் பெரும்பாடு
- 3.சேத்துமப் பெரும்பாடு
- 4.தொந்தப் பெரும்பாடு

**வாதப் பெரும்பாட்டின் குறிகுணங்கள்:**

தலைவலி, வயிற்றுக்கடுப்பு, உடல் கருத்தல் ஆகிய குறிகுணங்களைக் காட்டி செந்நிறமும் கருநிறமும் கலந்து குருதி வெளிப்படும்.

**பித்தப் பெரும்பாட்டின் குறிகுணங்கள்:**

அழகிய மஞ்சள் நிறத்துடன் கூடிய குருதி பாயும். யோனித்தாபிதம் ஏற்படும். கறுநிறத்துடன் கூடிய குருதிக் கட்டிகள் விழும்.

**சேத்துமப் பெரும்பாட்டின் குறிகுணங்கள்:**

வெண்மை நிறத்துடன் குருதி வெளிப்பாயும். துர்நாற்றம் மிகுந்திருக்கும். உடல் எல்லாம் சாம்பல் நிறமாகும்.

**தொந்தப் பெரும்பாட்டின் குறிகுணங்கள்:**

குருதி சிவப்பு நிறத்துடன் கூடிய கருப்பு நிறமுடன் கட்டிக் கட்டியாய் வெளிவரும். துர்நாற்றமிருக்கும்.

## **MENORRHAGIA**

### **DEFINITION:<sup>1</sup>**

Menorrhagia is defined as cyclic regular bleeding at normal intervals, the bleeding is either excessive in amount (>80ml) or duration (>7 days) or both.

### **CAUSES OF MENORRHAGIA:**

In 40-60% of women with menorrhagia no underlying cause is found. These women are said to have dysfunctional uterine bleeding.

### **UTERINE AND OVARIAN PATHOLOGIES:**

1. Uterine fibroids
2. Endometriosis
3. Adenomyosis
4. Pelvic inflammatory diseases
5. Pelvic infections
6. Endometrial hyperplasia or carcinoma
7. Polycystic ovarian disease.

### **SYSTEMIC DISEASES AND DISORDERS**

1. Coagulant disorder
2. Hypothyroidism
3. Liver or renal disease.

### **ITAROGENIC CAUSES:**

1. Anticoagulant therapy
2. Chemotherapy
3. IUCD (Intra uterine contraceptive device)

### **SYMPTOMS OF MENORRHAGIA:**

1. Excessive bleeding during menstruation
2. Prolonged menstruation
3. Blood clots
4. Anemia and Tiredness

## **Clinical Study**

The study was conducted on patients with Perumbadu (Menorrhagia). Patients satisfying the inclusion criteria were selected for trial. The study was conducted at the OPD of Ayothidoss Pandithar Hospital of the National Institute of Siddha, Tambaram Sanatorium, and Chennai-47.

Sample size: 20 patients.

### **SUBJECT SELECTION:**

#### **Inclusion criteria:**

- Age: 20-45 yrs
- Sex: Female
- Weight : >40 kgs
- Patient having symptoms of
  - Excessive bleeding
  - Prolonged menses ( bleeding > 7 days)
  - Blood clots
  - Anemia
  - Tiredness

Any of the above 4 clinical symptoms .

- Patient who are willing to provide blood sample for lab investigation.
- Patients who are willing to attend OPD once in 7 days.
- Patient willing to sign the informed consent stating that she will conscientiously stick to the treatment during 30 days but can opt out of the trial of her own conscious discretion.

#### **Exclusion criteria:**

- Fibroid uterus
- Carcinoma of uterus, cervix
- Endometriosis

- Pelvic inflammatory diseases
- Intra uterine contraceptive device.
- Hypothyroidism
- Polycystic ovarian disease.

**Withdrawal criteria:**

- Development of any adverse reaction
- Occurrence of any other serious illness
- Non co-operation of the patient

**TRIAL DRUG AND DURATION:**

Trial drug: Kuzhpaanda Chooranam, 1gm, bd with hot water after food.

Duration: 30 days.

**CONDUCT OF THE STUDY:**

Perumbadu patients satisfying the inclusion and exclusion criteria were admitted to the trial. Informed consent was obtained from the patient. Routine investigations like blood test, urine test were carried out before and after treatment. USG abdomen and Thyroid function tests were carried out before treatment. The patients were selected for OPD only. The trial drug was issued for seven days course. They were advised to visit the OPD in 7 days. At each visit they were clinically assessed.

**CLINICAL OBSERVATION:**

For the clinical study of Kuzhpaanda Chooranam on Perumbadu, 20 patients were selected. According to age wise distribution, 20 % was in 20-30 years, 80% was in 30-45 years.

Among the 20 patients, all of them were suffered from excessive bleeding, 75 % were suffered from prolonged menstruation, 90 % were suffered from blood clots, 85 % were suffered from tiredness and 60% were suffered from anemia.

From the clinical trial, 75% were relieved from excessive bleeding, 73 % were relieved from prolonged menstruation, 72% were relived from blood clots, 65% were relieved from tiredness and 58% showed improvement in hemoglobin level.

No adverse reactions were observed during the trial period.

(Refer Annexure Table 14 to Table 20)

## DISCUSSION

The drug Kuzhpaanda Chooranam was selected to find out the styptic activity in the Management of Perumbadu (Menorrhagia). The literary evidence from the text “Athmarakshamirtham ennum vaithiyasarasangirakam” strongly supports the styptic activity of the drug.

### **Biochemical analysis:**

The biochemical analysis of the drug reveals the presence of **Iron, Magnesium, Aluminium, Tannicacid, Calcium, Starch, Sugar and alkaloids.**

### **Tannic acid:**<sup>4,32</sup>

It has astringent activity. Traditional astringents are used to reduce blood loss from the reproductive tract. Astringents cause contraction or shrinkage of tissues thereby dry up secretions. It helps to clot blood.

### **Iron:**<sup>25</sup>

Iron can be taken as a supplement to make up for iron lost in heavy menstrual periods.

### **Magnesium:**<sup>26</sup>

Magnesium is a crucial constituent of the blood coagulation cascade. In clotting assays with dialysed plasma, addition of Mg<sup>2+</sup> ions enhanced the apparent coagulant activity of factor IXA while that of factor XA was scarcely affected.

### **Calcium:**<sup>27</sup>

Calcium is one among the XIII factors involved in the blood clotting mechanism.

1. The activated factor XI activates factor IX in the presence of factor IV (calcium).
2. Activated factor IX activates factor X in the presence of factor VIII and calcium.

**Aluminium:<sup>28</sup>**

Coagulation in vitro study showed that the clotting time is shortened to 21-32 sec by preincubation of the plasma with particulate substances such as kaolin (insoluble aluminium silicate).

**Atomic Absorption Spectrometer:**

The Atomic Absorption Spectrometer studies show the presence of metals Iron and Magnesium. Iron = 0.092 ppm, Magnesium = 0.135 ppm.

**High Performance Thin Layer Chromatography:**

The finger printing profile establish the identity and purity of the drug used. It is characteristic of each plant material used for pharmacological studies. The major peaks found in the finger print may be acidic glycosides or resins.

**Toxicological studies:**

Based on the toxicity study, no toxic effect was observed upto 400mg/kg of kuzhpaanda chooranam treated via oral route over a period of 28 days. So, it can be concluded that the kuzhpaanda chooranam can be prescribed for therapeutic use in human with the dosage recommendations of upto 400mg/kg. body weight p.o.

**Pharmacological studies:**

In the pharmacological study, Group II received Kuzhpaanda Chooranam at the dose of 200mg/kg. p.o., for three days exhibited significant ( $P < 0.01$ ) reduction in the duration of bleeding from the incised liver mechanical wound when compared to untreated normal and control animals. In conclusion, this study suggests that the Kuzhpaanda Chooranam is producing dose dependent styptic action and it can be clinically used as an Anti hemorrhagic agent after studying the systematic toxicity profile.

**Clinical observation:**

From the clinical study 75% of patients relieved from excessive bleeding, 73% of patients relieved from prolonged menstruation, 72% of patients relieved from blood clots, 58% of patients relieved from anemia, 65% of patients relieved from tiredness and no adverse effects were observed during trial period.

**Bio-statistics:**

The paired 't' test shows statistical significance in reduction of symptoms after treatment ( $p < 0.0001$ ).

**SIDDHA ASPECT**

1. குருதிப்பெருக்கடக்கி செய்கை உடையன<sup>4</sup>: பூசணிக்காய், கடுக்காய்

குருதிப்பெருக்கடக்கி (HAEMOSTATIC): குருதிப்போக்கைத் தடுக்கின்ற அல்லது உள் மரிக்கின்ற பொருள். (Drug that arrests or restrain bleeding.)

2. துவர்ப்பி செய்கை உடையன<sup>4</sup>: கடுக்காய், தான்றிக்காய், சீரகம்

துவர்ப்பி (ASTRINGENT): நரம்புகளையும், உடற்கட்டுகளையும் சுருக்கி குருதி, சீழ் முதலியவற்றை நிறுத்துகிற பொருள். (An agent that produces contraction or organic tissues thereby arrests haemorrhages, diarrhoea etc.)

3. பித்தநாசினி<sup>4</sup>: சீரகம்

பெரும்பாடு பித்தக் குற்றத்தின் கெடுதியால் உண்டாவதாகும்.

பித்தமகற்றி: பித்தத்தை அதிகப்படுத்தாமல் தணிக்கும் பொருள். (Drug that exerts soothing effect).

4. இனிப்பு சுவையை உடையன<sup>4</sup>: பூசணிக்காய், கடுக்காய், திப்பிலி, அதிமதுரம், சீரகம், சீனி.

இனிப்பு சுவையின் தொழில்<sup>29</sup>:

பித்தத் தோடம் தன்னிலை வளர்ச்சியடையின் அதனை தன்னிலைப்படுத்தும். உடற்கட்டுகளுக்கு வன்மையை கொடுக்கும்.



இனிப்பு: மண் + நீர்.

கருப்பை மண் பூதக்கூறாகும். இனிப்பும் மண் பூதக் கூறினைக் கொண்டது. எனவே பெரும்பாட்டிற்கு இனிப்பு சுவையை உடைய மூலிகைகளை வழங்கலாம்.

5. துவர்ப்பு சுவையை உடையன<sup>4</sup>: கடுக்காய், தான்றிக்காய்

துவர்ப்பு சுவையின் தொழில்<sup>29</sup>:

பித்தத்தைப் போக்கும். குருதியை தூய்மை செய்யும். உறுப்புகளைச் சுருங்கச் செய்யும்.

6. தட்ப வீரியத்தினை உடையன<sup>4</sup>: பூசணி, அதிமதுரம், சீனி, சீரகம்,

தட்ப வீரியத்தின் தொழில்<sup>29</sup>:

பித்தத்தைப் போக்கும்.

Hence, Kuzhpaanda Chooranam is a better drug of choice in the management of perumbadu.

## SUMMARY

The drug Kuzhpaanda Chooranam was selected to evaluate the styptic activity in the management of Perumbadu (Menorrhagia).

The literary evidence from “Athmarakshamirtham ennum vaithiyasara sangirakam” strongly supports the styptic activity of the drug.

The qualitative and quantitative analyses were done at Biochemistry lab, National Institute of Siddha and Sri Ramachandra Medical University, Chennai respectively. The biochemical analysis of the drug reveals the presence of **Iron, Magnesium, Aluminium, Tannicacid, Calcium, Starch, Sugar and alkaloids**. The results ensure the styptic activity of the Kuzhpaanda Chooranam was due to the presence of active phytoconstituents of the drug. High performance thin layer chromatography and atomic absorption spectrophotometer was done at Sri Ramachandra University, Chennai -52.

The pre-clinical evaluation (acute & repeated oral toxicity study) of the drug was carried out as per OECD guideline in Vels College of pharmacy, Chennai. The result shows safety of the drug for human administration.

The Preclinical Pharmacological study was carried out in animal model in Vels College of pharmacy, Chennai. The result shows that the drug has significant styptic effect.

As per the Siddha literature and modern science reviews and research articles, the trial drug has potent styptic effect.

20 Patients were recruited for clinical trial. The trial drug Kuzhpaanda Chooranam at the dose of 1 gm, b.i.d was given to the patient for 7 days and patients were asked to visit op once in 7 days for 30 days. Clinical assessment and prognosis was noted at each visit.

From the clinical study 75% of patients relieved from excessive bleeding, 73% of patients relieved from prolonged menstruation, 72% of patients relieved from blood clots , 58% of patients relieved from anemia, 65% of patients relieved from tiredness and no adverse effects were observed during trial period.

From the statistical analysis-paired't' test, the drug Kuzhpaanda Chooranam is statistically significant. The paired't' test shows statistical significance in reduction of symptoms after the treatment ( $p < 0.0001$ ).

The drug Kuzhpaanda Chooranam has

- Styptic Activity.
- No side effects
- No undoing effects
- Encouraging clinical results.

From the clinical study and statistical analysis it was proved that the drug Kuzhpaanda Chooranam was statistically significant on styptic activity in the management of perumbadu.

## CONCLUSION

- The literature evidence of the drug shows that it has styptic activity.
- The safety studies (acute toxicity and repeated oral toxicity) studies conducted revealed that the trial drug Kuzhpaanda Chooranam is safe. There were no abnormalities found in blood investigations and histo-pathological examination. Hence it can be reasonably assumed that the drug is safe for human use.
- The pharmacological study conducted in animal model shows significant styptic activity.
- Clinical study revealed the therapeutic efficacy of the trial drug by showing, reduction in symptoms after treatment. There was improvement in other clinical symptoms after treatment.
- There were no adverse reactions complained during the clinical trial.
- Hence, the drug KUZHPAANDA CHOORANAM can be used in the management of Perumbadu (Menorrhagia).

## INTRODUCTION<sup>31-35</sup>

Asthma is characterized by chronic airway inflammation and increased airway hyper-responsiveness leading to symptoms of wheeze, cough, chest tightness and dyspnoea. It is characterized functionally by the presence of airflow obstruction, which is variable over short period of time or is reversible with treatment.<sup>30</sup>

The prevalence of asthma increased steadily over the latter part of the last century in countries with a western lifestyle and is also increasing in developing countries. Current estimate suggest that 300 million people worldwide suffer from asthma and an additional 100 million may be diagnosed with asthma by the year 2025.

WHO (2012) fact sheet reveals that India has estimated 15-20 million asthma. Aggarwal et al has reported a prevalence of 2.38% in Indian population based on a survey conducted in Delhi, Chandigarh, Kanpur and Bangalore. According to an article published in Times of India, prevalence of asthma is 22% in Chennai.

Several factors have been contributed to the increased incidence of bronchial asthma. Food and inhalant allergens were of about equal importance in producing bronchial asthma between the ages of 15-55 years. Occupational asthma is now the most common form of occupational respiratory disorder and accounts for around 5% of all adult onset asthma. Increased environmental pollution particularly air pollution, lack of physical activity, increased urbanization, implementation of western culture, consumption of fast food, wide spread construction works, destruction of forest areas and poor health education among the affected individuals should be blamed for the high incidence of asthma.

Two third of all asthma cases are diagnosed before the patient is aged 18 years. The prevalence rate of severe asthma in industrialized countries ranges from 2-10%. Increased number of cases of bronchial asthma had been reported among employees of Chennai port and those in the neighborhood.

In Siddha system of medicine, Eraippu is clinically correlated with bronchial asthma. Among the three vital humors mentioned in siddha system, Eraippu occurs as a result of increased Kapham humour in our body. In siddha text “Gunapadam Mooligai Vaguppu” the combination of the herbal drug Notchi leaves (*Vitex negundo*), Poondur (*Allium sativum*), Milagu (*Piper nigrum*) and Lavangam (*Syzygium aromaticum*) is indicated for Eraippu noi.<sup>4</sup>

*Vitex negundo* has anti-asthmatic, bronchial relaxant and anti-histaminic activities. *Piper nigrum* has anti-asthmatic and analgesic activities. *Syzygium aromaticum* has anti-inflammatory and antimicrobial activities. *Allium sativum* has expectorant property.

Regarding the taste, kaarppu suvai, veppa veerium and kaarppu pirivu is common among all the four ingredients.<sup>4</sup> Kaarppu suvai neutralizes or nullifies the kapha kuttram thereby reduces the exacerbation of attacks<sup>29</sup>. In addition to this all the four ingredients are easily available and cost wise it is very cheap.

Hence the author has selected this poly herbal preparation to evaluate its bronchodilator activity and its therapeutic effect in Eraippu noi (bronchial asthma).

## **AIM AND OBJECTIVE**

### **AIM**

To evaluate the safety and efficacy of Eraippu Mathirai for Bronchodilator and Anti-histaminic activity in the management of Eraippu (Bronchial asthma).

### **OBJECTIVE**

#### **PRIMARY OBJECTIVE:**

To evaluate the Bronchodilator activity and Antihistaminic activity of Eraippu mathirai for Eraippu in preclinical studies.

#### **SECONDARY OBJECTIVE:**

The efficacy of Eraippu Mathirai has been evaluated in the following aspects.

1. Collection of evidences in siddha aspect and botanical aspect.
2. Standard operative procedures.
3. Physical properties.
4. Biochemical analysis.
5. High performance thin layer chromatography
6. Clinical study- a pilot study on trial medicine.

## **MATERIALS AND METHODS**

### **STANDARD OPERATIVE PROCEDURE:**

#### **Collection and Authentication of the raw drugs:**

The raw drugs were procured from the indigenous raw drug store in Chennai. Notchi leaves were collected from the local garden in Thiruvottriyur, Chennai-19. The authentication was got from the competent authority of Gunapadam Department, National Institute of Siddha, Chennai.

#### **Ingredients:**

Purified Notchi leaves (*Vitex negundo*)

Purified Milagu (*Piper nigrum*)

Purified Poondur (*Allium sativum*)

Purified Lavangam (*Syzygium aromaticum*)

All are in equal amount.

#### **Purification process:**

Purification of Notchi leaves:

The mid rib of the leaves was removed.

Purification of Milagu:<sup>6</sup>

The raw drug was purified by soaking it in butter milk for 1 hour 15 minutes and then dried well.

Purification of Poondur:

The outer layer was peeled off.

Purification of Lavangam:<sup>6</sup>

The raw drug was purified by drying it in sunlight.



**Preparation of the medicine:**

Purified Milagu and lavangam were powdered finely and purified garlic was crushed separately. First the notchi leaves were placed in the kalvam and it was ground well. Then the powdered raw drug materials and the crushed Garlic were placed in a kalvam. This mixture was ground well using juice of notchi leaves and it was made into the karkam form. Pills weighing about 130 mg were made from the karkam and dried well and then stored in an air tight container.

**LABELLING:**

Name of the preparation	:	Eraippu Mathirai
Quantity of the drug	:	28 pills
Date	:	May 28 <sup>th</sup> , 2012
Dose	:	2 pills, bds, chewable
Indication	:	Eraippu
Date of expiry	:	1 year from the date of preparation.



மிளகு (*Piper nigrum*)



இலவங்கம் (*Syzygium aromaticum*)



நொச்சி (*Vitex negundo*)



பூண்டு (*Allium sativum*)



ERAIPPU MATHIRAI

## 1.நொச்சி<sup>4</sup>

**வேறு பெயர்கள்:** நிர்க்குண்டி, இந்திரசூரியம்

**பயன்படும் உறுப்பு:** இலை

**சுவை:** கசப்பு, துவர்ப்பு, கார்ப்பு, **தன்மை:** வெப்பம், **பிரிவு:** கார்ப்பு

**செய்கை:**

உடல்தேற்றி

புழுவகற்றி

**பொதுகுணம்:**

நோயா கலியை நொடிக்கு ளருந்தவெம்மை

யோயா மணாளு முயர்த்துதலுக் - காய

வந்தமுதல் நண்பாகி வாதத்தை யேயுறவாற்

சிந்துவா ரங்கனலுந் தீ.

**பயன்கள்:**

வளிச்சுரங்கள், குளிர்சுரம், முறைசுரம் தணியும்.

**நொச்சி இலை சேரும் இரைப்பு நோய்க்கான பிற மருந்துகள்:**

1.மகாவாதத்திற்கு எண்ணெய்: 1 கழஞ்சு சாப்பிட ஈளை, இருமல் தீரும்.<sup>36</sup>

2.நொச்சி எண்ணெய்: 1-2 தேக்கரண்டி வெந்நீரில் சாப்பிட இளைப்பு, சுவாசம் தீரும்.<sup>8</sup>

3.கடகரை எண்ணெய்: அளவு போல் சாப்பிட்டு வர இருமல், இரைப்பு தீரும்.<sup>37</sup>

4.வாசாதி லேகியம்: 1/4 பலம் தினம் 2 வேளை சாப்பிட சுவாசகாசம், கயரோகம் தீரும்.<sup>11</sup>

5.அவரி நெய்: 1 கரண்டி வீதம் 1 வேளை சாப்பிட்டு வர ஈளை, இருமல் தீரும்.<sup>3</sup>

## 2.மிளகு<sup>4</sup>

வேறு பெயர்கள்: மலையாளி, சருமபந்தம்.

பயன்படும் உறுப்பு: விதை, பழம்

சுவை: கசப்பு, கார்ப்பு

தன்மை: வெப்பம்

பிரிவு: கார்ப்பு

செய்கை: முறைவெப்பகற்றி, காறலுண்டாக்கி

பொதுகுணம்:

சீதசுரம் பாண்டு சிலேத்துமங் கிராணிகுன்மம்  
வாதம் அருசிபித்தம் மாமூலம் - ஓதுசன்னி  
யாசமபஸ் மாரம் அடன்மேகம் காசமிவை  
நாசங் கறிமிளகினால்.

பயன்கள்: வளி, தீ கபக்குற்றங்கள் அனைத்தையும் நீக்கும்.

மிளகு சேரும் இரைப்பு நோய்க்கான பிற மருந்துகள்:

1. அஷ்டசிந்தாதி லேகியம்: குன்றி பிரமாணம் 2 வேளை உண்ண சுவாசகாசம், இருமல் தீரும்.<sup>38</sup>
2. குக்கிலாதி மாத்திரை: கழற்சிக்காயளவு தினம் 1 உருண்டை சாப்பிட சுவாசகாசம், குன்மம் தீரும்.<sup>39</sup>
3. வில்வமுதலி இளகம்: நாள்தோறும் 3 கழஞ்சு உட்கொள்ள ஈளை, இருமல் தீரும்.<sup>40</sup>
4. மகாதாளிசைச் சூரணம்: வெருகடி பிரமாணம் 2 வேளை உண்ண ஈளை, மூர்ச்சை தீரும்.<sup>38</sup>
5. முத்தச் சூரணம்: தினமும் எலுமிச்சங்காயளவு உண்டு வர ஈளை, வாந்தி தீரும்.<sup>12</sup>

### 3.பூண்டு<sup>4</sup>

பயன்படும் உறுப்பு: கிழங்கு

வேறு பெயர்கள்: இலசனம், காயம்

சுவை:கார்ப்பு

தன்மை: வெப்பம்

பிரிவு: கார்ப்பு

செய்கை: கோழையகற்றி, வெப்பமுண்டாக்கி

குணம்:

சன்னியொடு வாதந் தலைநோவு தாள்வலி  
மன்னிவரு நீர்க்கோவை வன்சீதம்- அன்னமே  
உள்ளுள்ளி கண்பாய் உளைமூல ரோகமும்போம்  
வெள்ளுள்ளி தன்னால் வெருண்டு.

பயன்கள்: இருமல், இரைப்பு நீங்கும்.

**பூண்டு சேரும் இரைப்பு நோய்க்கான பிற மருந்துகள்:**

- 1.ஆடாதோடை நெய்: 1/2-1 தேக்கரண்டி 3 வேளை தினமும் கொடுக்க இரைப்பு, இருமல் தீரும்.<sup>8</sup>
- 2.கருங்கோழி பற்பம்: குளிகைகள் செய்து பசுநெய்யில் சாப்பிட சுவாசகாசம் நிங்கும்.<sup>39</sup>
- 3.கழலைக்கு எண்ணெய்: நாள்தோறும் உட்கொள்ள மிகத்தீவிரமான ஈளை, இருமல் தீரும்.<sup>40</sup>

## 4. இலவங்கம்<sup>4</sup>

பயன்படும் உறுப்பு: பூ

வேறு பெயர்கள்: திரளி, அஞ்சுகம்

சுவை: விறுவிறுப்பு, கார்ப்பு

தன்மை: வெப்பம்

பிரிவு: கார்ப்பு

செய்கை: அகட்டுவாய்வகற்றி, இசிவகற்றி

பொதுகுணம் :

பித்தமயக்கம் பேதியோடு வாந்தியும் போம்  
சுத்தவிரத் தக்கடுப்புந் தோன்றுமோ- மெத்த  
இலவங்கங் கொண்டவருக் கேற் சுகமாகும்  
மலமங்கே கட்டுமென வாழ்த்து.

பயன்கள்: மயக்கம், பேதி, வாந்தி தீரும்.

**இலவங்கம் சேரும் இரைப்பு நோய்க்கான பிற மருந்துகள்:**

1. பஞ்சபரணச் சூரணம்: மூவிரல் கொண்ட அளவு தினம் 1 வேளை சாப்பிட சுவாசகாசம், பாண்டு தீரும்.<sup>40</sup>
2. சிஞ்சாதி லேகியம்: கொட்டைப்பாக்களவு 1 மண்டலம் சாப்பிட இரைப்பு, காமாலை தீரும்.<sup>40</sup>
3. தூதுகண்டன் கிருதம்: கொட்டைப்பாக்களவு 1 மண்டலம் சாப்பிட ஈளை, இளைப்பு தீரும்.<sup>15</sup>
4. ஆம்பல் சூரணம்: தினம் காலை, இரவு உண்டு வர இளை, நீரிழிவு நீங்கும்.<sup>12</sup>
5. அழுக்கரா சூரணம்: 1-2 கி தேனில் இருவேளை உண்ண இரைப்பு, வெள்ளை தீரும்.<sup>8</sup>

## BOTANICAL ASPECT

### 1. *Vitex negundo*<sup>19</sup>

#### **Vernacular names:**

Eng: Five Leaved Chest Tree, Hindi: Samhalu, Mal: Karunocci, Tel : Nallavavilli, Kan: Niragundi, Sans: Nirgundi, Sugandhika

#### **Classification:**<sup>18</sup>

Kingdom: Plantae  
Division: Magnoliophytae  
Class: Magnoliopsida  
Subclass: Asteridae  
Order: Lamiales  
Family: Verbanaceae  
Genus: *Vitex*  
Species: *Vitex negundo*

#### **BOTANICAL DESCRIPTION:**

Laves petiolate, digitately compound; leaflets 3-5, lanceolate or elliptic-lanceolate, unequal, entire or coarsely crenate-serrate, acute to acuminate, nearly glabrous above, tomentose beneath.

#### **PART USED:**

Leaf

#### **CHEMICAL CONSTITUENTS:**

A glycoside 2'-p-hydroxybenzoylmussaenosidic acid, two glycosidic iridoids viz. nishindaside and negundoside, 5,3'-dihydroxy-7,8,4'- and 5,3'-dihydroxy-6,7,4'-trimethoxyflavones, two flavonoids viz. 5-hydroxy-3,6,7,3',4'-pentamethoxyflavone and 3,5'-dihydroxy 3',4',6,7-tetramethoxyflavonol.

**PHARMACOLOGICAL ACTIVITIES:**

Antiinflammatory, antihistamine releasing activity, analgesic, antispasmodic, and antimicrobial.

**ACTIONS AND USES:**

The leaves are aromatic, tonic, vermifuge and useful in rheumatism, catarrhal fever, cephalagia, inflammations and ulcers.

**SUPPORTIVE JOURNAL ARTICLES:**

1. Evaluation of the anti-asthmatic activity of leaves of vitex negundo.<sup>58</sup>  
-Asian journal of pharmaceutical and clinical research.
2. Antihistaminic activity of vitex negundo and quantitative phytochemical analysis of hydro alcoholic extracts of vitex negundo.<sup>59</sup>  
-International journal of research in pharmaceutical and biomedical sciences.
3. Evaluation of the effect of vitex negundo leaves extract on bronchoconstriction and bronchial hyper reactivity in experimental animals.  
-pharmacology online.<sup>60</sup>

**2. Piper nigrum<sup>19</sup>****VERNACULAR NAMES:**

Eng: Black pepper, Hindi: Mirch, Sans: Maricha, Kan: Miri, Mal: Kurumulaku, Tel: Miriyalu.

**CLASSIFICATION:<sup>18</sup>**

Kingdom: Plantae  
Division: Magnoliophyta  
Class: Dicotyledons  
Subclass: Magnoliidae  
Order: Piperales  
Family: Piperaceae



Genus: Piper  
Species: Piper nigrum

**PART USED:**

Fruit

**BOTANICAL DESCRIPTION:**

Fruits ovoid or globose, one seeded bright red when ripe. Seeds globose, testa thin, perisperm hard and white.

**PHYSICAL CONSTANTS:**

Total ash-not more than 5%, acid insoluble ash-not more than 0.5%, alcohol soluble extractive-not less than 6%, water soluble extractive- not less than 6%.

**CHEMICAL CONSTITUENTS:**

Piperine, piperonal, piperoleine A and B, pellitorine, piperettine, citronellol, cryptone, arginine, pipercolic acid, serine, ascorbic acid, carotene.

**PHARMACOLOGICAL ACTIVITIES:**

Antiinflammatory, antipyretic, antimicrobial, analgesic, anticonvulsant.

**ACTIONS AND USES:**

Fruits are acrid, bitter, stimulant and digestive. They are useful in asthma, fever, cough, dyspepsia and convulsions.

**SUPPORTIVE JOURNAL ARTICLES:**

1. Piperine- exhibits anti-asthmatic effect and antioxidant effect. Improves the bioavailability of other nutritive substances.<sup>61</sup>

-International journal of pharmaceutical sciences.

2. Antiasthmatic effect of fruit extract of Piper nigrum.<sup>62</sup>

-International journal of Herbal Drug Research.

3. Piperine inhibits eosinophil infiltration and airway hyper responsiveness by suppressing T cell activity and Th2 cytokine production in the ovalbumin induced asthma model.<sup>63</sup>

-Journal of Pharmacy and Pharmacology.

### **3. *Allium sativum*<sup>19</sup>**

#### **VERNACULAR NAMES:**

Eng: Garlic, Hindi: Lahsan, Sans: Lashuna, Uragandha, Tel: Velluli, Mal: Nelluthulli, Kan: Balluci.

#### **CLASSIFICATION:<sup>18</sup>**

Kingdom: Plantae

Division: Magnoliophyta

Class: Monocotyledons

Subclass: Liliidae

Order: Liliales

Family: Liliaceae

Genus: *Allium*

Species: *Allium sativum*

#### **PART USED:**

Bulb

#### **BOTANICAL DESCRIPTION:**

Bulbs 2-4 cm in diam. with many fleshy, creamy, ovoid bulblets or cloves having peculiar alliaceous pungent odour; bulbs covered by outer white thin scales.

#### **PHYSICAL CONSTANTS:**

Foreign matter- not more than 2%, total ash- not more than 4%, acid insoluble ash- not more than 1%, alcohol soluble extractive- not less than 2.5%.

**CHEMICAL CONSTITUTENTS:**

Diallyl trisulphide, diallyl sulphide, diallyl disulphide, allyl methyl trisulphide, alliinase, allitin, allicin, alliin, allixin, scordinine A, A1, A2 and B.

**PHARMACOLOGICAL ACTIVITIES:**

Antiinflammatory, antioxidant, antitubercular, hepatoprotective, antifungal.

**ACTIONS AND USES:**

Bulbs are acrid, bitter, astringent, anodyne, and expectorant. It is useful in asthma, hiccough, cough, whooping cough, bronchitis and malarial fever. The sulphur containing compounds in garlic (*Allium sativum*) are useful mucolytic agents. When the dysulphur of allyl is liberated through the breath it acts directly on the bronchial mucus membrane

#### **4. *Syzygium aromaticum*<sup>19</sup>**

**VERNACULAR NAMES:**

Eng: Cloves, Hindi: Lavanga, Sans: Varija, Chandanapushpaka, Kan: Lavanga, Mal: Karampu, Tel: Lavangalu.

**CLASSIFICATION:<sup>18</sup>**

Kingdom: Plantae

Division: Magnoliophyta

Class : Dicotyledons

Subclass: Rosidae

Order : Myrtales

Family : Myrtaceae

Genus : *Syzygium*

Species : *Syzygium aromaticum*

**PART USED:**

Flower buds

**BOTANICAL DESCRIPTION:**

Flower buds greenish to pink, aromatic, clustered at the ends of branches.

**PHYSICAL CONSTANTS:**

Foreign matter- not more than 2%, total ash- not more than 7%, acid insoluble ash- not more than 1%, alcohol soluble extractive- not less than 3%, water soluble extractive- not less than 9%, volatile oil- not less than 15%.

**CHEMICAL CONSTITUENTS:**

Polyoxygenated chromone C-glucoside, isobiflorin, biflorin, eugenol, acetyl eugenol, acetyleneugenol, caryophyllene, ellagitannin, eugenin, eugenol acetate.

**PHARMACOLOGICAL ACTIVITIES:**

Histamine release inhibitory activity, anticonvulsant, antioxidant, antimicrobial.

**ACTIONS AND USES:**

The cloves are acrid, bitter, expectorant, stomachic and antispasmodic. It is useful in asthma, cough, bronchitis, sore throat and tuberculosis. Caryophyllene in flower buds exhibits antiasthmatic and antispasmodic activities.

## **PHYSICAL PROPERTIES OF ERAIPPU MATHIRAI**

The Physical properties of Eraippu Mathirai were analysed in the following procedure. It was done at SriRamachandra University, Chennai.

### **Materials and Methods:**

#### **pH at 10% of aqueous solution:**

Five grams of Eraippu Mathirai was weighed accurately and placed in clear 100 ml beaker. Then 50 ml of distilled water was added to it and dissolved well. After 30 minutes it was then applied in to pH meter at standard buffer solution of 4.0, 7.0, and 9.2.

#### **Ash Values**

The Ash values are a measure of the inorganic constituents present in the raw drug. A high ash content explains its unsuitable nature to be used as a drug.

#### **Total Ash**

A little of extract was taken in a silica crucible previously ignited, cooled and weighed. It was incinerated by gradually increasing the heat not exceeding dull red heat (450°C) until free from carbon, cooled and weighed. The percentage of ash was calculated with reference to air- dried drug. The procedure was repeated to get the constant weight.

#### **Water soluble ash**

The total ash was boiled with 25 ml water and filtered through ash less filter paper (Whatmann 4.1). It was followed by washing with hot water .The filter paper was dried and ignited in the silica crucible, cooled and the water insoluble ash was weighed. The water-soluble ash can be calculated by subtracting the water insoluble ash from the total ash.

**Acid insoluble ash**

The total ash obtained was boiled for 5 minutes with 25 ml of (10% w/v) dilute hydrochloric acid and filtering through ash less filter paper (Whatmann 4.1). The filter paper was ignited in the silica crucible, cooled and insoluble ash was weighed.

(Refer Annexure Table 23)

# HIGH PERFORMANCE THIN LAYER CHROMATOGRAPHY

HPTLC of Eraippu Mathirai was done at Sri Ramachandra University, Chennai.

## HPTLC Fingerprint - RH1

### Sample Preparation

100 mg of extract was weighed and dissolved in 70% methanol to get a concentration of 10mg/ml concentration this is then used for injection.

### CHROMATOGRAPHIC CONDITION FOR HPTLC FINGER PRINT

SampleName	:	Eraippu Mathirai
Sample-ID	:	112
Stationary phase	:	Silica gel F 254
Mobile phase	:	n-Hexane: Ethyl acetate: Formic acid 60:40:2.5 ml)
Scanning wavelength	:	254,298,489 nm
Sample concentration	:	20 mg/ml
Injecting volume	:	5, 10 µl
Development mode	:	ascending mode

### Significance of HPTLC fingerprinting in Standardisation

Standardisation of traditional medicine has become mandatory in the present national and international scientific scenario, as they have to stand competing with stringent regulatory methods and also clinically. HPTLC is one of the versatile chromatographic methods presently available for the rapid analysis of herbal drugs due to several reasons. Firstly the time required for the demonstration of the most of the characteristic constituents of a drug is very quick and short. Secondly, in addition to qualitative detection, HPTLC also provides semi-quantitative information on the major active constituents of a drug, thus enabling an assessment of drug quality. Thirdly the fingerprint obtained is suitable for monitoring the identity and purity of drugs and for detecting adulteration and substitution. Hence in order to check the identity, purity and standardise the quantity of active principles in the herbal extracts a HPTLC fingerprint of all the 12 ingredient medicinal plants used in the formulation has been obtained.

The distribution of phyto-constituents in a plant depends on various factors such as soil, time of collection period of storage, etc. So, it is necessary to standardize the extract being used for pharmacological studies. HPTLC serves as a convenient tool for finding out the distribution pattern of phyto constituents which is unique to each plant. The HPTLC finger-printing profile establishes the identity and purity of the raw drug being used. It helps in the authentication of the plant material.

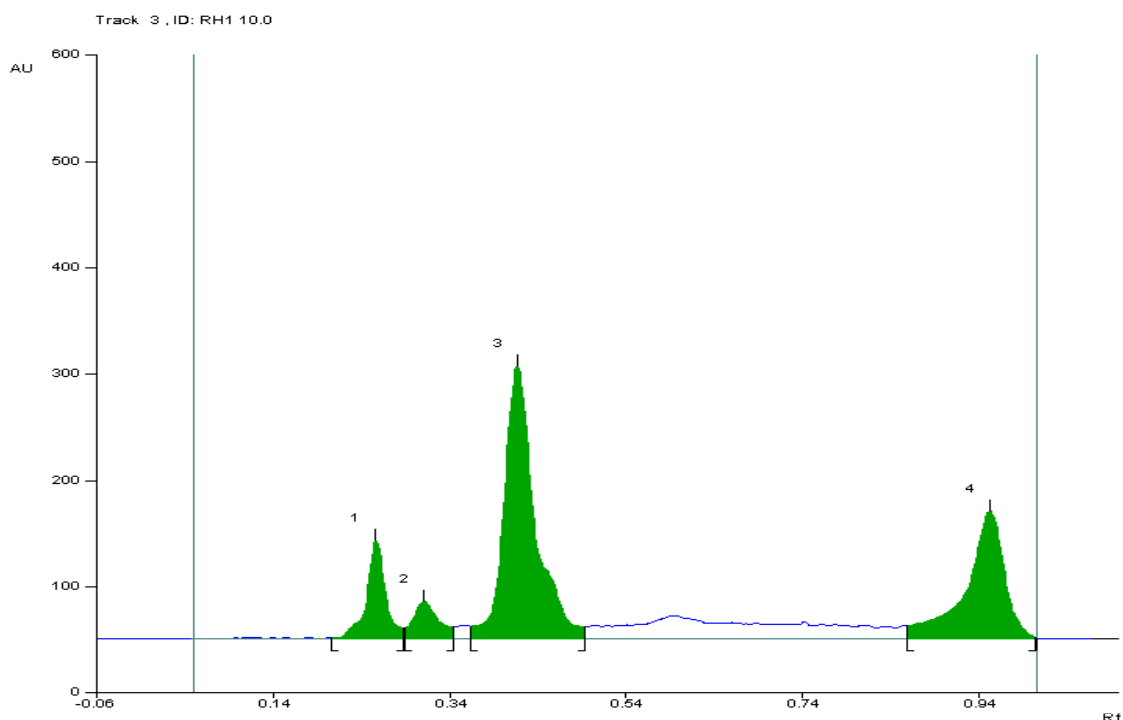
### **Chromatographic Conditions**

The finger printing has been done using the following chromatographic conditions. Chromatography was performed on a 10x10 cm pre activated HPTLC silica gel 60F 254 plate. Samples were applied to the plate as 6mm wide band with an automatic TLC applicator Linomat 5 with N<sub>2</sub> flow (CAMAG, Switzerland), 8mm from the bottom. Densitometric scanning was performed on CAMAG scanner III. The plates were pre-washed by methanol and activated at 60<sup>0</sup> C for 5 minutes prior to chromatography. The slit dimension was kept at 5 minutes x 0.45 minutes and 20 minutes scanning speed was employed. The mobile phase was chosen after running each plant in different mobile phases of varying polarity (Toluene, Toluene: Ethyl acetate and Ethyl acetate: Methanol) and 10 ml of mobile phase was used per chromatography. Linear ascending development was carried out in 20 cm x 10-cm twin glass chamber saturated with the mobile phase.

### **Chromatographic Analysis**

The hydro alcoholic extracts of the plants have been prepared at a concentration of 10 mg/10 ml in alcohol and were spotted using CAMAG Linomat 5 applicator. The method was optimized by selecting appropriate mobile phase for respective plant extracts and developed in a twin trough chamber, 20 x 10 cm at 25<sup>0</sup>C. The plates were dried by hair dryer. The developed plates were scanned at appropriate wavelength using CAMAG TLC scanner 3 and photo-documented using CAMAG REPROSTAR 3.





### Inference

HPTLC fingerprint of RH -1 shows four peaks at Rf values 0.25, 0.31, 0.41 & 0.95. The peak correspond to the Rf value 0.31 has maximum peak area of 7256.5. At this stage it is difficult to confirm the individual components present in the extract, but from our lab experience on phytochemical analysis, we suggest that the major peaks found in the fingerprint may be acidic glycosides / resins. Since, in the present chromatographic conditions, the above mentioned components will be eluted easy.

Refer Annexure Fig.112-01 to Fig.112-12)

## BIO -CHEMICAL ANALYSIS OF ERAIPPU MATHIRAI

The biochemical analysis of the Eraippu Mathirai was carried out in the Biochemistry lab, National Institute of Siddha, Chennai.

S.No	EXPERIMENT	OBSERVATION	INFERENCE
1.	Appearance of sample	Brown colour	
2.	<b>Solubility:</b> a. A small amount of the sample was shaken well with distilled water. b. A small amount of the sample was shaken well with con. HCl/Con. H <sub>2</sub> SO <sub>4</sub>	Sparingly soluble	Absence of Silicate
3.	<b>Action of Heat:</b> A small amount of the sample was taken in a dry test tube and heated gently at first and then strong.	No white fumes evolved	Absence of Carbonate
4.	<b>Flame Test:</b> A small amount (500mg) of the sample was made into a paste with con. HCl in a watch glass and introduced into non-luminous part of the Bunsen flame.	No Bluish green flame appeared.	Absence of Copper
5.	<b>Ash Test:</b> A filter paper was soaked into a mixture of sample and dil.cobalt nitrate solution and introduced into the Bunsen flame and ignited.	Yellow colour flame not appeared.	Absence of sodium

### Preparation of Extract:

5gm of Eraippu Mathirai was weighed accurately and placed in a 250ml clean beaker 50ml of distilled water is added. Then it was boiled well for about 10 minutes. Then it was cooled and filtered in a 100ml volumetric flask and made up to 100ml with distilled water.

S.No	EXPERIMENT	OBSERVATION	INFERENCE
	<b>I. Test For Acid Radicals</b>		
1.	<b>Test For Sulphate:</b> a. 2ml of the above prepared extract was taken in a test tube. To 2ml of 4% dil ammonium oxalate solution was added. b. 2ml of the above prepared extract was added with 2ml of dil-HCl until the effervescence ceases off. Then 2ml of dil.Barium chloride solution was added.	No Cloudy appearance	Absence of Sulphate
2.	<b>Test For Chloride:</b> 2ml of the above prepared extract was added with dil. HCl till the effervescence ceases. Then 2ml of dil.silver nitrate solution was added.	No cloudy appearance	Absence of Chloride
3.	<b>Test For Phosphate:</b> 2ml of the extract was treated with 2ml of dil.ammonium molybdate solution and 2ml of con.HNO <sub>3</sub> .	No Yellowish Appearance	Absence of Phosphate
4.	<b>Test For Carbonate:</b> 2ml of the extract was treated with 2ml dil. Magnesium sulphate solution	No Cloudy appearance.	Absence of carbonate
5.	<b>Test For Nitrate:</b> 1gm of the substance was heated with copper turning and concentrated H <sub>2</sub> SO <sub>4</sub> and viewed the test tube vertically down.	No Brown gas evolved.	Absence of Nitrate
6.	<b>Test For Sulphide:</b> 1gm of the substance was treated with 2ml of con. HCL	No Rotten Egg Smelling gas.	Absence of Sulphide
7.	<b>Test For Fluoride &amp; Oxalate:</b> 2ml of extract was added with 2ml of dil. Acetic acid and 2ml dil.calcium chloride solution and heated.	No Cloudy appearance	Absence of fluoride and oxalate
8.	<b>Test For Nitrite:</b> 3 drops of the extract was placed on a filter paper, on that-2	No Characteristic changes	Absence of Nitrite

	drops of dil.acetic acid and 2 drops of dil.Benzidine solution was added.		
9.	<b>Test For Borate:</b> 2 Pinch (50mg) of the substance was made into paste by using dil.sulphuric acid and alcohol (95%) and introduced into the blue flame.	No Bluish green colour flame.	Absence of borate
	<b>II. Test For Basic Radicals</b>		
1.	<b>Test For Lead:</b> 2ml of the extract was added with 2ml of dil.potassium iodine solution.	No yellow Precipitate obtained.	Absence of Lead
2.	<b>Test For Copper:</b> One pinch (50mg) of substance was made into paste with con. HCl in a watch glass and introduced into the non-luminous part of the flame.	No Blue colour flame No Blue colour precipitate formed.	Absence of copper
3.	<b>Test For Aluminium:</b> To the 2ml of extract, dil.sodium hydroxide was added in 5 drops to excess.	Yellow colour not appeared.	Absence of aluminium
4.	<b>Test For Iron:</b> a. To the 2ml of extract, 2ml of dil.ammonium solution was added. b. To the 2ml of extract 2ml thiocyanate solution and 2ml of conc. HNO <sub>3</sub> was added	Blood red colour appeared.	Presence of Iron
5.	<b>Test For Zinc:</b> To 2ml of the extract, dil.sodium hydroxide solution was added in 5 drops to excess and dil.ammonium chloride was added.	White precipitate was not formed	Absence of Zinc
6.	<b>Test For Calcium:</b> 2ml of the extract was added with 2ml of 4% dil.ammonium oxalate solution	Cloudy appearance and white precipitate was not obtained	Absence of calcium
7.	<b>Test For Magnesium:</b> To 2ml of extract dil.sodium hydroxide solution was added	White precipitate was not obtained	Absence of Magnesium

	in drops to excess.		
8.	<b>Test For Ammonium:</b> To 2ml of extract 1 ml of Nessler's reagent and excess of dil.sodium hydroxide solution are added.	No Brown colour appeared	Absence of ammonium
9.	<b>Test For Potassium:</b> A pinch (25mg) of substance was treated of with 2ml of dil.sodium nitrite solution and then treated with 2ml of dil.cobalt nitrate in 30% dil.glacial acetic acid.	No Yellowish precipitate was obtained.	Absence of Potassium
10.	<b>Test For Sodium:</b> 2 pinches (50mg) of the substance was made into paste by using HCl and introduced into the blue flame of Bunsen burner.	Yellow colour flame not appeared	Absence of sodium
11.	<b>Test For Mercury:</b> 2ml of the extract was treated with 2ml of dil.sodium hydroxide solution.	No yellow precipitate was obtained	Absence of mercury
12.	<b>Test For Arsenic:</b> 2ml of the extract was treated with 2ml of dil.sodium hydroxide solution.	No brownish red precipitate was obtained	Absence of arsenic
	<b>III. Miscellaneous</b>		
1.	<b>Test For Starch:</b> 2ml of extract was treated with weak dil.iodine solution	No blue colour developed	Absence of starch
2.	<b>Test For Reducing Sugar:</b> 5ml of Benedict's qualitative solution was taken in a test tube and allowed to boil for 2 minutes and added 8 to 10 drops of the extract and again boil it for 2 minutes. The colour changes are noted.	No Brick red colour developed	Absence of reducing sugar
3.	<b>Test For The Alkaloids:</b> a) 2ml of the extract was treated with 2ml of dil.potassium iodide solution. b) 2ml of the extract was treated with 2ml of dil.picric acid.	Yellow colour developed	Presence of Alkaloid

	c) 2ml of the extract was treated with 2ml of dil.phosphotungstic acid.		
4.	<b>Test For Tannic Acid:</b> 2ml of extract was treated with 2ml of dil.ferric chloride solution	No black precipitate	Absence of Tannic acid
5.	<b>Test For Unsaturated Compound:</b> To the 2ml of extract 2ml of dil.Potassium permanganate solution was added.	Potassium permanganate was not decolorized	Absence of unsaturated compound
6.	<b>Test For Amino Acid:</b> 2 drops of the extract was placed on a filter paper and dried well. 20ml of Biurette reagent was added.	violet colour not developed	Absence of amino acids
7.	<b>Test For Type Of Compound:</b> 2ml of the extract was treated with 2 ml of dil.ferric chloride solution.	<p>No green colour developed</p> <p>No red colour developed</p> <p>No violet colour developed</p> <p>No blue colour developed</p>	<p>Absence of oxy quinole pinephrine and pyro catechol</p> <p>Anti pyrine, Aliphatic amino acids and meconic acid are absent</p> <p>Apomorphine salicylate and Resorcinol are absent</p> <p>Morphine, Phenol cresol and hydroquinone are absent</p>

(Refer Annexure Table 24)

## **TOXICITY STUDY**

### **ACUTE AND SUB ACUTE TOXICITY STUDIES OF ERAIPPU MATHIRAI IN RODENTS:**

#### **ANIMALS**

Mice of either sex weighing 25-30g and rats weighing 210-240g were obtained from the animal house of Vels University. The animals were used with the approval of the Institute animal ethics committee and obtained from Vels University, Chennai. They were fed with a balanced standard pellet diet and maintained under standard laboratory conditions, providing 24-28<sup>0</sup>C temperature, standard light cycle (12 h light, 12 h dark) and water ad libitum.

Animals were kept in cages with raised floors of wide mesh to prevent coprophagy. Animal welfare guidelines were observed during the maintenance period and experimentation. The rats were randomly assigned to control and different treatment groups, six animals per group. The animals were acclimatized for one week under laboratory conditions.

(Registration no - XIII/VELS/PCOL/40/2000/CPCSEA/IAEC/08.08.2012).

#### **ACUTE TOXICITY STUDY-OECD 425 GUIDELINES:**

Acute oral toxicity test for the Eraippu Mathirai was carried out as per OECD Guidelines 425. As with other sequential test designs, care was taken to ensure that animals are available in the appropriate size and age range for the entire study. The test substance was administered in a single dose by gavage using a stomach tube or a suitable intubation cannula. The fasted body weight of each animal was determined and the dose is calculated according to the body weight. After the substance has been administered, food was withheld for a further 2 hours in mice. The animals were observed continuously for the first 4 h and then each hour for the next 24 h and at 6 hourly intervals for the following 48 h after administering of the test drug, to observe any death or changes in general behaviour and other physiological activities.

Single animals were dosed in sequence usually at 48 h intervals. However, the time interval between dosing is determined by the onset, duration, and severity of toxic

signs. Treatment of an animal at the next dose was delayed until one is confident of survival of the previously dosed animal.

**Observation of toxicity signs:** General behavior, respiratory pattern, cardiovascular signs, motor activities, reflexes, change in skin and fur, mortality and the body weight changes were monitored daily. The time of onset, intensity, and duration of these signs, if any, was recorded.

## **SUB-ACUTE TOXICITY**

In a 28-days sub acute toxicity study, twenty four rats of either sex were divided into four groups of 6 rats each. Group I that served as normal control was administered with distilled water (p.o.) while groups II, III and IV were administered daily with the Eraippu Mathirai (p.o.) for 28 days at a dose of 100, 200 and 400 mg/kg respectively. The animals were then observed daily for gross behavioural changes and any other signs of subacute toxicity.

The weight of each rat was recorded on day 0 and weekly throughout the course of the study, food and water consumption per rat was calculated. At the end of the 28 days they were fasted overnight, each animal was anaesthetized with diethylether, following which they were then dissected and blood samples were obtained by cardiac puncture into heparinised tubes. The blood sample collected from each rat was centrifuged with 3000 X g at 4°C for 10 min to separate the serum and used for the biochemical assays.

## **Hematological and blood biochemical analysis:**

At the end of the study, all animals were kept fasted for 16-18 h and then anesthetized with anesthetic ether on the 28th day. Blood samples for hematological and blood chemical analyses were taken from retro orbital vein. Heparinized blood samples were taken for determining complete blood count (white blood cell count, differential white blood cell count, platelet count, red blood cell count, hematocrit, and hemoglobin) by semiautomated hematology analyzer.

The serum from non-heparinized blood was carefully collected for blood chemistry and enzyme analysis like glucose, Creatinine, Total protein, Albumin, Total and Direct bilirubins, Serum glutamate-oxaloacetate transaminase (SGOT), Serum



glutamate pyruvate transaminase (SGPT), and Alkaline phosphatase (ALP) were automatically determined using autoanalyzer.

### **Necropsy:**

All rats were sacrificed after the blood collection. The positions, shapes, sizes and colors of internal organs were evaluated. The Spleen, Testes, Pancreas, Lung, Liver, Brain, Heart, Stomach, Intestine, Bone, Ovary, and Kidney tissues were excised from all rats to visually detect gross lesions, and weighed to determine relative organs' weights and preserved in 10% neutral formalin for histopathological assessment. The tissues were embedded in paraffin, and then sectioned, stained with haematoxylin and eosin and were examined microscopically.

### **Statistical analysis**

Values were represented as mean  $\pm$  SEM. Data were analysed using one-way analysis of variance (ANOVA) and group means were compared using the Tukey-Kramer Multiple Comparison test using Instat-V3 software. P values < 0.05 were considered significant.

## **RESULTS AND DISCUSSION**

In the acute toxicity study at the dose level of 5g/kg moderate toxic symptoms like tremor, writhing and diarrhea was observed. Hence the next lower dose 2g/kg was tried and confirmed the non toxic response to test drug Eraippu Mathirai. Hence for the further study the one tenth, one fifth and one twentieth of the tolerable dose was selected for the further sub acute toxicity evaluation.

In the sub acute toxicity study, animals were not shown any significant toxic clinical signs during the dosing period of 28 days. All animals from control and all the treated dose groups survived throughout the dosing period of 28 days. Results of body weight determination of animals of control and different dose groups exhibited comparable body weight gain throughout the dosing period of 28 days. During dosing period, the quantity of food consumed by animals from different dose groups was found to be comparable and normal with that of control animals.

Macroscopic examination of animals in control and test product– treated groups did not reveal any major and remarkable abnormality. These tests conducted on the

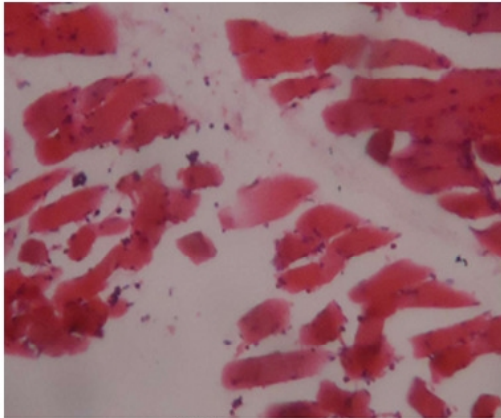
experimental animals at termination and recorded did not reveal any abnormalities. Urine analysis data treated group of animals did not reveal any specific abnormalities. Relative Organ Weights are normal except testes ( $P<0.01$ ) and liver ( $P<0.05$ ). Comparison of organ weights of treated animals with respective control animals on day 28 was found to be comparable. Gross pathological examination of animals in control as well as the treated groups did not reveal any abnormalities. The results of haematological investigations, revealed significant reduction in the values of platelet count only when compared with control and no other remarkable changes was observed in haematological profile. Results of Biochemical investigations revealed the significant changes in the values of globulin level at moderate and high dosing groups when compared with those of respective controls; however, the values obtained were within normal biological and laboratory limits ( $P<0.01$ ).

#### **CONCLUSION:**

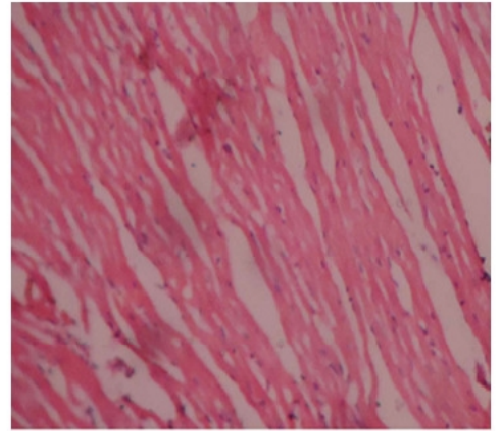
Based on these findings, no toxic effect was observed upto 400mg/kg of *Eraippu Mathirai treated* via oral route over a period of 28 days. So, it can be concluded that the *Eraippu Mathirai* can be prescribed for therapeutic use in human with the dosage recommendations of upto 400mg/kg. body weight p.o.

**\*\***(Refer Annexure Table 27 to Table 36)

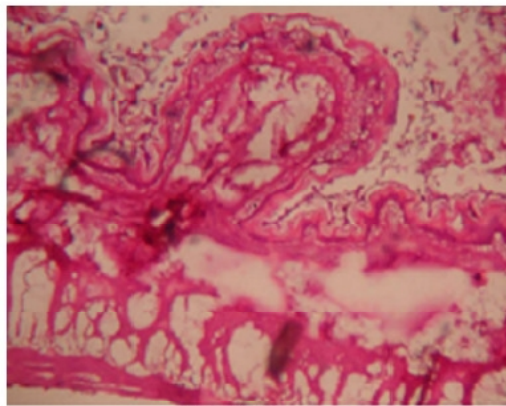
## HISTOPATHOLOGY SLIDES



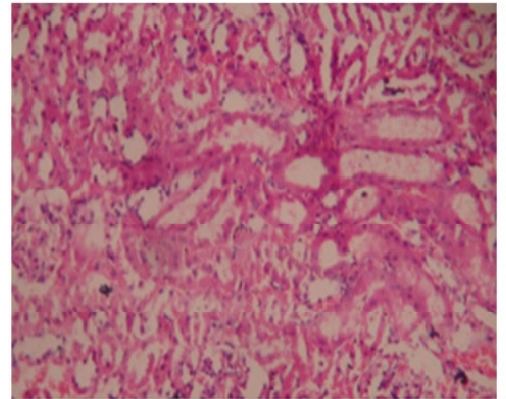
BONE



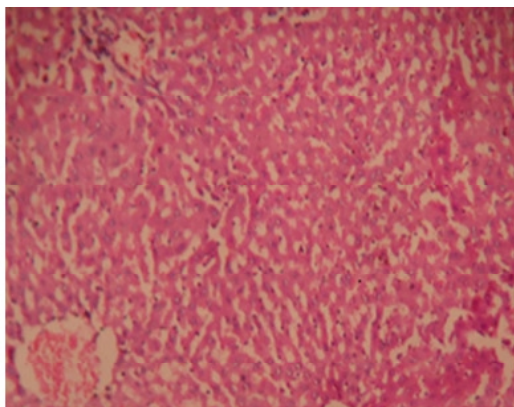
HEART



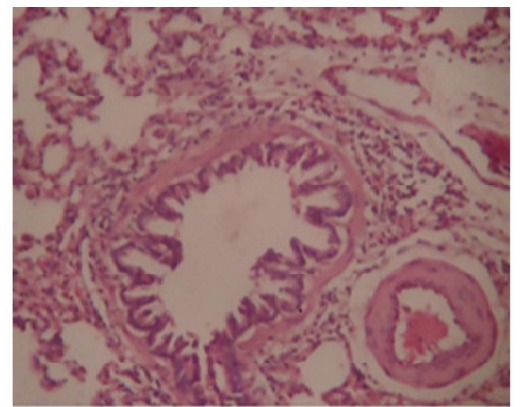
INTESTINE



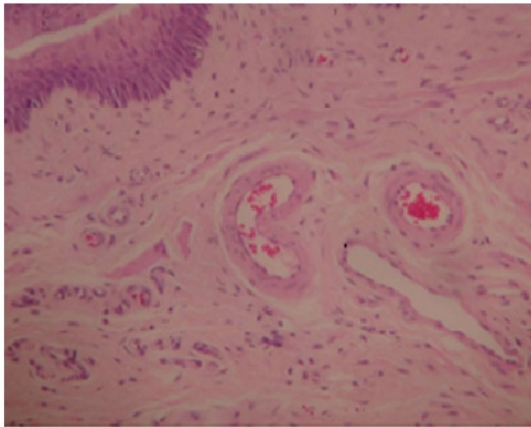
KIDNEY



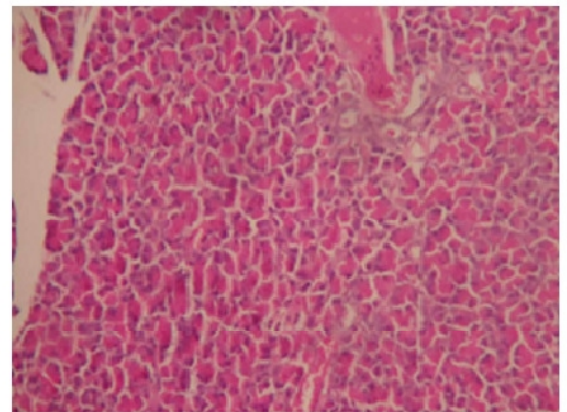
LIVER



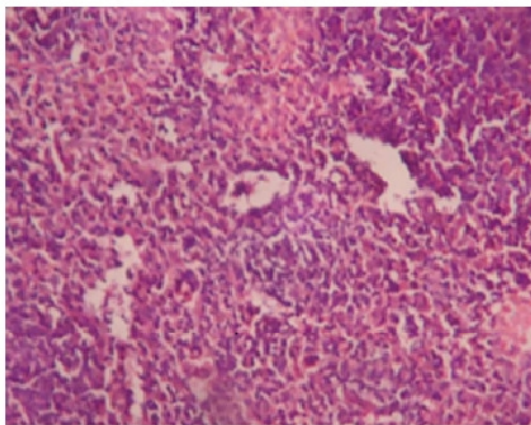
LUNG



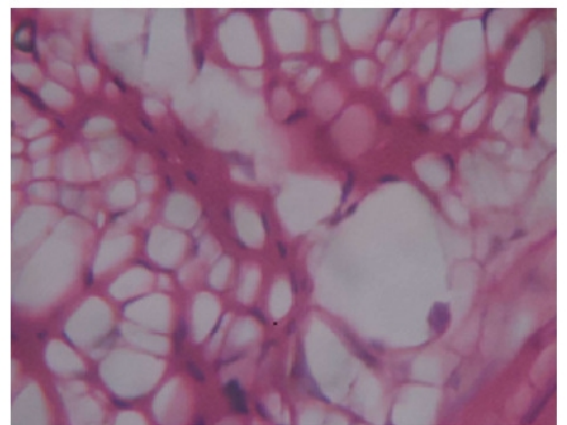
OVARY



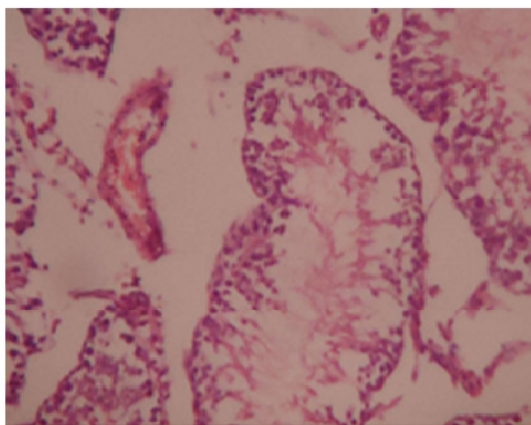
PANCREAS



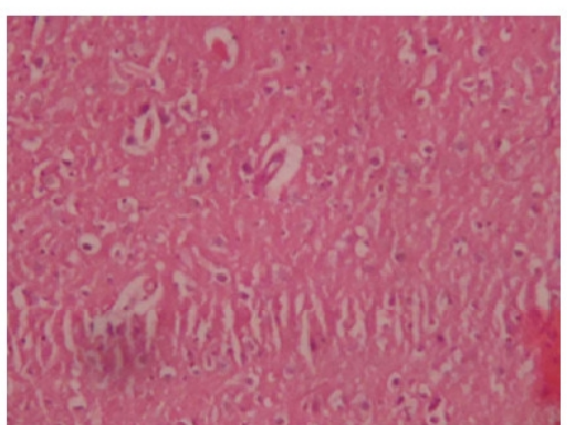
SPLEEN



STOMACH



TESTIS



BRAIN

## PHARMACOLOGICAL STUDY<sup>41-53</sup>

### BRONCHODILATOR AND ANTIHISTAMINIC ACTIVITY OF ERAIPPU MATHIRAI

#### MATERIALS AND METHODS:

##### Drugs and Stock Solution

Drugs used were Histamine diphosphate (Sigma Chemical, USA) and Promethazine hydrochloride (Rhone – Poulenc, Mumbai). Histamine dihydrochloride was dissolved in distilled water and desired concentrations were prepared. The test drug Eraippu Mathirai concentration was 100 microgram per ml prepared by suspending with 2% CMC and then the volume was adjusted to 10 ml with normal saline for making the concentration of 100 µg/ml in distilled water.

##### Animals

Male albino guinea pig weighing 350– 400g was kept in fasting condition 18 hours prior to commencement of experiment and given water ad libitum. It was housed under standard laboratory conditions of temperature ( $25 \pm 2^{\circ}\text{C}$ ) and 12/12 hr light/dark cycle and then sacrificed by a blow to the head and exsanguinated as per CPCSEA recommended guidelines. (XIII/VELS/PCOL/40/2000/CPCSEA/IAEC/08.08.2012)

##### In-vitro antihistaminic study

Guinea pig was sacrificed and a segment of ileum (2 cm) was dissected from the terminal ileum and mounted in an organ bath containing Tyrode solution (10 ml) between two stainless steel hooks under 0.5 to 1 g initial tension. The lower hook was fixed at the bottom of the organ bath and upper one was connected to an isotonic transducer. The Tyrode solution composition (pH 7.4) was (concentration in gm/lit.) NaCl 8.0, KCl 0.2,  $\text{CaCl}_2$  0.2,  $\text{MgCl}_2$  0.1,  $\text{NaHCO}_3$  1.0,  $\text{NaH}_2\text{PO}_4$  0.05, and Glucose 1.0 gm/liter. It was continuously aerated and maintained at  $37 \pm 0.5^{\circ}\text{C}$ . The equilibrium period was 60 min and the bath solution was refreshed every 15 min. After equilibrium period, a dose response curve for histamine in variant molar concentrations, by maintaining 45 min time cycle.



## **BRONCHODILATOR STUDY**

Experimental bronchial asthma was induced in guinea pigs by exposing them to histamine. Overnight fasted guinea pigs of either sex (350-450) were selected and randomly divided into four groups each consisting of six animals. Group 1-3 was treated as Test group and received of Eraippu Mathirai at the dose levels of (100-400mg/kg). Group 4 was considered as standard and administered with Promethazine (300mg/kg, p.o). All the doses were given orally.

Prior to drug treatment each guinea pigs were exposed to an atomized fine mist of 2% w/v histamine dihydrochloride aerosol (dissolved in normal saline) using a nebulizer in the histamine chamber. Guinea pigs exposed to histamine aerosol showed progressive signs of difficulty in breathing leading to convulsions, asphyxia and death. Once the animal fell on its back, it was immediately taken out of the chamber and exposed to fresh air where the animal returned back to normal. After 1 hour the animals in the first three groups were administered orally 100, 200 and 400 mg/kg p.o, of Eraippu Mathirai respectively. While the fourth group of animal received 300µg/kg of Promethazine by oral route. The time until signs of convulsion appeared is called pre-convulsion time (PCT) and was determined from the time of exposure to onset of convulsions.

As soon as pre convulsion time was noted, animals were removed from the chamber and placed in fresh air to recover. The percentage protection offered by treatment was calculated by using the following formula: Percentage protection =  $(1 - T_1/T_2) \times 100$ . Where;  $T_1$  = the mean of PCT of control group animals.  $T_2$  = the mean of PCT of test group animals.

### **Statistical analysis**

Data were expressed as Mean  $\pm$  SEM. Differences between groups were analyzed by one way analysis of variance (ANOVA) followed by Dunnet “t” test. Differences were considered significant when  $P < 0.05$  and  $P < 0.01$ .

## **RESULTS AND DISCUSSION**

Histamine causes contraction of guinea pig ileum. Eraippu Mathirai showed a dose dependent inhibition of the contractions induced by Histamine on guinea pig ileum.

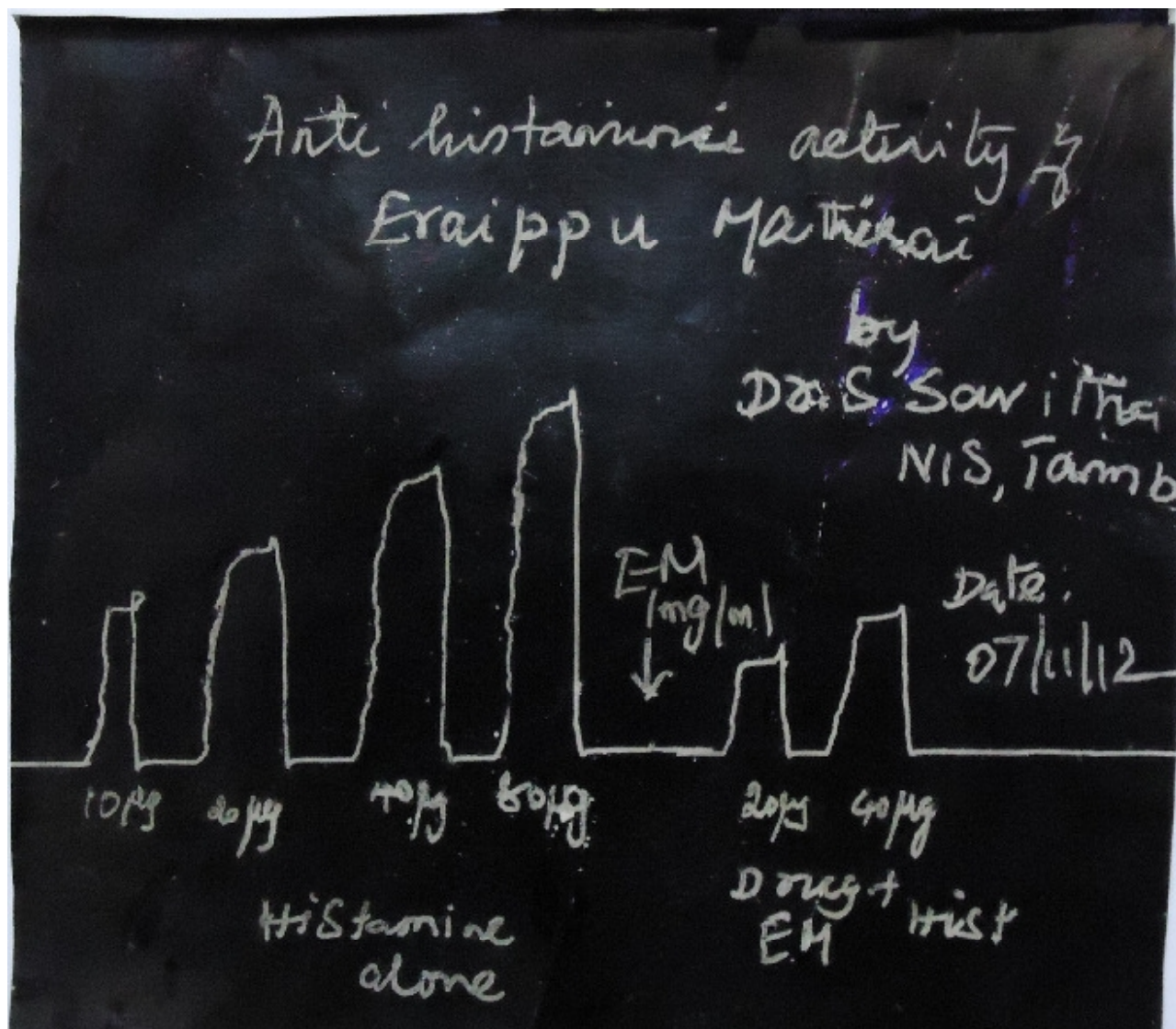
Bronchodilators help in clearing mucus from the lungs. As the airways opens, the mucus moves more freely and can be coughed out more easily. In short-acting forms,

bronchodilators relieve or stop asthma symptoms and are very helpful during an asthma episode. In long-acting forms, bronchodilators provide control of asthma symptoms and prevent asthma episodes. The ability of the Eraippu Mathirai to inhibit the contraction induced by the bronchoconstrictor histamine suggests a possible role in the treatment of asthma. In the invitro antihistaminic study the test drug shifted the curve towards right indicates the antagonistic property. Similarly, bronchodilator evaluation results revealed that the low dose of Eraippu Mathirai exhibited 21.92% of activity and median and high dose showed 23.42 and 31.95% respectively which is comparable to that of standard drug promethazine (37.13%). Airway responsiveness in asthma is attributed in part to changes in autonomic regulation particularly increased parasympathetic activity. Bronchoconstriction or airway hyper-responsiveness in asthma are believed to be a direct consequence of airway wall inflammation. Eraippu Mathirai was more effective in inhibiting the contractions of histamine and also produces bronchodilation *invivo*.

## CONCLUSION

The results of this study showed a relatively potent antihistaminic and bronchodilatory effect of Eraippu Mathirai (both *In vivo* and *In vitro*). These activities justify the traditional use of this drug in the treatment of bronchoconstrictive diseases and can be used at the dose level used in this study based on the severity of the disease clinically.

# ANTI-HISTAMINIC ACTIVITY OF ERAIPPU MATHIRAI



\*\*(Refer Annexure Fig.2, Fig.3 and Table 25, Table 26)



## இரைப்பு நோய்<sup>54</sup>

**வேறு பெயர்கள்:** இழுப்பு நோய், சுவாசம், தொய்வு, ஈளை, சுரம், சுவாசகாசம்.

### இயல்பு:

இந்நோய் யாதொரு காரணமுமின்றி மார்பை வலித்து இறுக்கியது போன்ற வேதனையைத் தந்து, மூச்சை வெளியிடவும், உள்ளே இழுக்கவும் முடியாமற்றிணரச் செய்யும். அன்றியும் வெளியாகும் மூச்சு மிகுந்த சிரமத்துடன் வெளியாவதுடன் குழல், யாழ், வீணை முதலிய வாத்தியங்களின் ஒலியைப் போல் ஒலிக்கும். மேலும், மார்பிலுள்ள சளியை இருமி வெளியாக்க முயன்றாலும் அக்கோழை எளிதில் வெளியாவதில்லை.

### நோய் வரும் வழிகள்:

- 1.உடற்கு ஒவ்வாத உணவு, செயல் முதலியவற்றாலும்
- 2.ஐயத்தை மிகுதிப்படுத்தக்கூடிய உணவாலும், நடத்தையாலும்
- 3.புல், பூண்டு, நெல், அரிசி, கேழ்வரகு முதலியவைகளின் சுணையாலும்
- 4.தனக்கு ஒவ்வாத நாற்றப் பொருள்களை முகர்வதாலும் இந்நோய் பிறக்கும்
- 5.நாட்பட்ட இருமல்
- 6.அதிசீதள நீரையருந்துதல்
- 7.வாந்தியினால்
- 8.பாண்டு ரோகத்தினால்
- 9.அருவருப்பாகிய புகையை சுவாசிப்பதாலும்
- 10.குளிர்ந்த கீழ்க்காற்றினாலும்

இரைப்பு நோய் உண்டாகும்.

### நோயின் குறிகுணங்கள்:

- 1.மூக்கில் நீர்பாய்தல்
- 2.தும்மல்
- 3.மார்பு நோதல்
- 4.மார்பை இறுக்கிக் கட்டியது போலிருத்தல்

- 5.இயற்கை மூச்சானது தடைப்படல்
- 6.விலாப்பக்கம் வலித்து மூச்சுத் திணறல்
- 7.வயிறுப்பல்
- 8.உடல் வியர்த்தல்
- 9.மூச்சு விடவும், உள்வாங்கவும் முடியாமல் வேதனைப்படும்
- 10.படுக்கையில் பொருந்தாமை

#### நோய் வகை:

- 1.வளி இரைப்பு (சிற்றிரைப்பு)
- 2.ஐய இரைப்பு (மந்தார இரைப்பு)
- 3.ஐயவளி இரைப்பு (பேரிரைப்பு)
- 4.முக்குற்ற இரைப்பு (திணறலிரைப்பு)
- 5.மேல்நோக்கு இரைப்பு (மேலிரைப்பு)

#### முக்குற்ற வேறுபாடுகள்:

- 1.மார்பிடமான அநாகதத்தில் "மேல்நோக்குங்கால்" தன் அளவில் மிகுந்து நிற்கும்.
- 2.வளியும் ஐயமும் சேர்ந்த மிகுதியே காரணமாகும்.
- 3.வாயுவால் தூண்டப்பட்ட பித்தத்தினால் இரைப்பு நோயுண்டாகும்.

#### நாடி நடை:

1. "கபமல்லாது காச சுவாசம் காணாது"
2. பாங்கான வாதத்தில் சேத்தும நாடி  
.....  
வாங்கான ஈளை மந்தார காசம்
3. பித்தமே மிகுந்த லீளை  
யிருமலும் பெலத்து நிற்கும்.

## **BRONCHIAL ASTHMA<sup>30,55,56</sup>**

Asthma is a chronic reversible inflammatory destructive disease of the airways characterized by recurrent paroxysmal attacks of dyspnoea chiefly expiratory in nature accompanied by wheeze which may subside spontaneously or with treatment.

### **AETIOLOGY:**

#### **1. ALLERGENS:**

Allergens may be inhaled or ingested. Inhaled allergens are house dust, pollens, dander, feather etc. Ingested allergens include various substances such as egg, fish, crab, chocolates, aspirin, penicillin, iodide etc. This type of allergic asthma develops in atopic individuals mediated by antibodies. These antibodies belong to a type of immunoglobulin called IgE - this is called type I hypersensitivity reaction. The antigen antibody reaction causes degranulation of the mast cells which releases pharmacologically active substances producing bronchiolar spasm and obstruction.

#### **2. INFECTION:**

Infection of the bronchial mucosa causes airway obstruction due to edema of the mucosa and overproduction of mucus.

#### **3. EXERCISE:**

It may precipitate asthma or may worsen the asthmatic attacks.

#### **4. PSYCHOLOGICAL FACTORS:**

Emotional stress may precipitate an attack.

#### **5. TEMPERATURE AND HUMIDITY:**

Changing temperature and humidity may cause obstruction to the airways in the asthmatic subjects.

#### **6. SMOKING:**

Cigarette smoking also causes airway obstruction.

**TYPES OF ASTHMA:**

1. Extrinsic asthma
2. Intrinsic asthma

**EXTRINSIC ASTHMA:**

Onset is in childhood. It occurs in atopic individuals who readily form IgE antibodies in response to allergens.

**INTRINSIC ASTHMA:**

It can begin at any age, especially in late adulthood. There is no role for allergens in the production of the disease.

**CLINICAL FEATURES:**

1. Cough with or without sputum.
2. Shortness of breath that gets worse with exercise or activity.
3. Pulling in of the skin between the ribs when breathing (intercostals retraction).
4. Wheezing
5. Abnormal breathing pattern.
6. Chest pain.
7. Chest tightness.

**EMERGENCY SYMPTOMS:**

1. Bluish color to the lips and face.
2. Decreased level of alertness, such as severe drowsiness or confusion, during an asthma attack.
3. Extreme difficulty breathing.
4. Rapid pulse.
5. Severe anxiety due to shortness of breath.

**COMPLICATIONS:**

1. Secondary infections such as bronchitis, tuberculosis.
2. Emphysema of lungs
3. Cor pulmonale.

4. Permanent changes in the functions of the lungs.
5. Bronchiectasis
6. Pneumothorax.

## CLINICAL STUDY

The study was conducted on patients with Eraippu noi (Bronchial asthma). Patients satisfying the inclusion criteria were selected for trial. The study was conducted at the OPD/IPD of Ayothidoss Pandithar Hospital of the National Institute of Siddha, Tambaram Sanatorium, and Chennai-47.

Sample size: 20 patients.

### SUBJECT SELECTION:

#### Inclusion criteria:

- Age: 20-65 yrs
- Sex: Male and Female
- Weight: 35-85 kgs
- Patient having symptoms of
  - Wheezing
  - Dyspnoea
  - Cough
  - Cough with expectoration
  - Chest tightness

Any of the above 4 clinical symptoms.

- Patient who are willing to provide blood sample for lab investigation.
- Patients who are willing to attend OPD once in 7 days.
- Patient who are willing to be admitted in the hospital for 30 days.
- Patient willing to sign the informed consent stating that he/she will conscientiously stick to the treatment during 30 days but can opt out of the trial of his/her own conscious discretion.

#### Exclusion criteria:

- Smoking/Alcohol Consumption
- Acute asthma
- Cardiac asthma
- Renal asthma

- Any other serious illness

**Withdrawal criteria:**

1. Development of any adverse reaction
2. Occurrence of any other serious illness
3. Non co-operation of the patient.

**TRIAL DRUG AND DURATION:**

Trial drug: Eraippu Mathirai, 2 pills, bd, chewable after food.

Duration: 30 days.

**CONDUCT OF THE STUDY:**

Patients with Eraippu noi satisfying the inclusion and exclusion criteria were admitted to the trial. Informed consent was obtained from the patient. Routine investigations like blood test, urine test were carried out before and after treatment. ECG and Chest X-ray was done before treatment. For IP patients the drug was administered daily. For OP patients the trial drug was issued for seven days course. They were advised to visit the OPD in 7 days. At each visit they were clinically assessed.

**CLINICAL OBSERVATION:**

For the clinical study of Eraippu Mathirai on Eraippu 20 patients were selected. Among the 20 patients, 10 were male (50%), 10 were female (50%). According to age wise distribution, 25 % were in 20 - 30 years, 45 % were in 30-45 years, 30 % were in 45-60 years.

Among the patients, all of them suffered from wheezing, 80% suffered from prolonged Dyspnoea, 75% suffered from cough, 80% suffered from expectoration and 80% suffered from chest tightness.

From the clinical trial, 75% were relieved from wheezing, 69% were relieved from Dyspnoea, 73% were relived from cough, 75% were relieved from expectoration and 69% were relieved from chest tightness.

16 (80%) patients had significant increase in peak expiratory flow rate after treatment.

No adverse reactions were observed during the trial period.

\*\*(Refer Annexure Table 37 to Table 41)



## DISCUSSION

The drug Eraippu Mathirai was selected to find out the bronchodilator activity and anti-histaminic activity in the management of Eraippu (bronchial asthma). The literary evidence from the text Gunapadam mooligai vaguppu strongly supports the anti-histaminic and bronchodilator activity of the drug.

### Biochemical analysis:

The biochemical analysis of the drug reveals the presence of **iron and alkaloids**.

#### Iron:<sup>27</sup>

It is required for the formation of haemoglobin. Haemoglobin and myoglobin are required for the transport of oxygen and carbondioxide. Haemoglobin increases the oxygen carrying capacity of blood. It is associated with the immuno competence of the body.

### High Performance Thin Layer Chromatography:

The finger printing profile establish the identity and purity of the drug used. It is characteristic of each plant material used for pharmacological studies. The major peaks found in the finger print may be acidic glycosides or resins.

### Toxicological studies:

Based on the results of toxicity studies, no toxic effect was observed upto 400mg/kg of *Eraippu Mathirai treated* via oral route over a period of 28 days. So, it can be concluded that the *Eraippu Mathirai* can be prescribed for therapeutic use in human with the dosage recommendations of upto 400mg/kg. body weight p.o.

### Pharmacological studies:

The results of the pharmacological studies showed a relatively potent antihistaminic and bronchodilatory effect of Eraippu Mathirai (both *In vivo* and *In vitro*). These activities justify the traditional use of this drug in the treatment of bronchoconstrictive diseases and can be used at the dose level used in this study based on the severity of the disease clinically.

**Clinical observation:**

From the clinical study 75% of patients relieved from wheezing, 69% of patients relieved from dyspnoea, 73% of patients relieved from cough, 75% of patients relieved from expectoration, 69% of patients relieved from chest tightness and no adverse effects were observed during trial period.

16 (80%) patients had a significant increase in the PEFr after treatment.

**Bio-statistics:**

Statistically, the paired 't' test shows statistical significant improvement in PEFr and reduction in clinical symptoms after treatment. ( $p < 0.0001$ )

## SIDDHA ASPECT<sup>4</sup>

### 1.நொச்சி

சுவை: கைப்பு, கார்ப்பு, துவர்ப்பு, தன்மை:வெப்பம், பிரிவு: கார்ப்பு

### 2.மிளகு:

சுவை: கைப்பு, கார்ப்பு, தன்மை:வெப்பம், பிரிவு: கார்ப்பு

### 3.பூண்டு

சுவை:கார்ப்பு, தன்மை:வெப்பம், பிரிவு: கார்ப்பு

### 4.இலவங்கம்:

சுவை:கார்ப்பு, விறுவிறுப்பு, தன்மை:வெப்பம், பிரிவு: கார்ப்பு

கார்ப்பு சுவையின் தொழில்:<sup>29</sup> :

கபத்தால் உண்டான கெடுதல்களை நீக்கும். தொண்டையில் உண்டாகும் பிணிகள் நீங்கும். கபத்தை சமப்படுத்தும்.

கைப்பு சுவையின் தொழில்: கபபித்தங்களை சமப்படுத்தும்.

வெப்ப வீரியத்தின் தொழில்: கபத்தை நீக்கும்.

"கபமல்லாது காசசுவாசம் காணாது"

எனவே கபக்குற்றத்தின் கெடுதியை முதன்மையாக கொண்டு வரும் இரைப்பு நோயினை கார்ப்பு, கைப்பு சுவை மற்றும் வெப்ப வீரியம் முதலியவற்றை உடைய மூலிகைகளை கொண்டு பரிகரிக்கலாம்.

## SUMMARY

The drug Eraippu Mathirai was selected to evaluate the anti-histaminic and bronchodilator activity in the management of Eraippu (Bronchial asthma). The literary evidence from Gunapadam Mooligai Vaguppu strongly support the antihistaminic and bronchodilator activity of the drug.

The qualitative and quantitative analyses were done at Biochemistry lab, NIS and Sri Ramachandra University, Chennai respectively. The biochemical analysis of the drug reveals the presence of iron and alkaloids. The results ensure the anti-histaminic and bronchodilator activity of the Eraippu Mathirai was due to the presence of active phytoconstituents of the drug. HPTLC was done at Sri Ramachandra University, Chennai.

The pre-clinical evaluation (acute & repeated oral toxicity study) of the drug was carried out as per OECD guideline in Vels College of pharmacy, Chennai. The result shows safety of the drug for human administration. The Preclinical Pharmacological study was carried out in animal model in Vels College of pharmacy, Chennai. The result shows that the drug has significant anti-histaminic and bronchodilator effect.

As per the Siddha literature and modern science reviews and research articles, the trial drug has potent anti-histaminic and bronchodilator effect. 20 Patients were recruited for clinical trial. The trial drug Eraippu Mathirai at the dose of 260 mg, b.i.d was given to the patient for 7 days and patients were asked to visit once in 7 days for 30 days. Clinical assessment and prognosis was noted at each visit.

From the clinical study 75% of patients relieved from wheezing, 69% of patients relieved from dyspnoea, 73% of patients relieved from cough, 75% of patients relieved from expectoration, 69% of patients relieved from chest tightness and no adverse effects were observed during trial period.

16 patients (80%) had a significant increase in the PEF after treatment.

Statistically, the paired 't' test shows statistical significant improvement in PEFR and reduction in symptoms after treatment. ( $p < 0.0001$ )

The drug Eraippu Mathirai has

- Bronchodilator and Anti-histamine ( $H_1$ -receptor antagonism) Activity.
- No side effects
- No undoing effects
- Encouraging clinical results.

From the clinical and statistical analysis it is proved that the drug Eraippu Mathirai is statistically significant on bronchodilator and anti-histaminic activity in the management of Eraippu (Bronchial Asthma).

## CONCLUSION

- The literature and research journal review of the plant shows that it has anti-histaminic and bronchodilator activity.
- The safety studies (acute toxicity and repeated oral toxicity) studies conducted revealed that the trial drug Eraippu Mathirai is safe. There were no abnormalities found in blood investigation and histo-pathological examination. Hence it can be reasonably assumed that the drug is safe for human use.
- The pharmacological study conducted in animal model shows significant anti-histaminic and bronchodilator activity.
- Clinical study revealed the therapeutic efficacy of the trial drug by showing, reduction in Absolute Eosinophil Count Levels and improvement in Peak Expiratory Flow Rate level significantly. There was improvement in other clinical symptoms after treatment.
- There were no adverse reactions complained during the clinical trial.
- Hence, the drug ERAIPPU MATHIRAI can be used in the management of Eraippu (Bronchial asthma).

## KUZHPAANDA CHOORANAM

**Table 1. Physical Properties**

S.No	Characteristic test	Results
1.	pH	4.32
3.	Ash value	0.93 (g/g of Sample)
4	Water soluble ash	0.01 (g/g of Sample)
5	Acid insoluble ash	0.02 (g/g of Sample)

**Table 2. Qualitative Analysis**

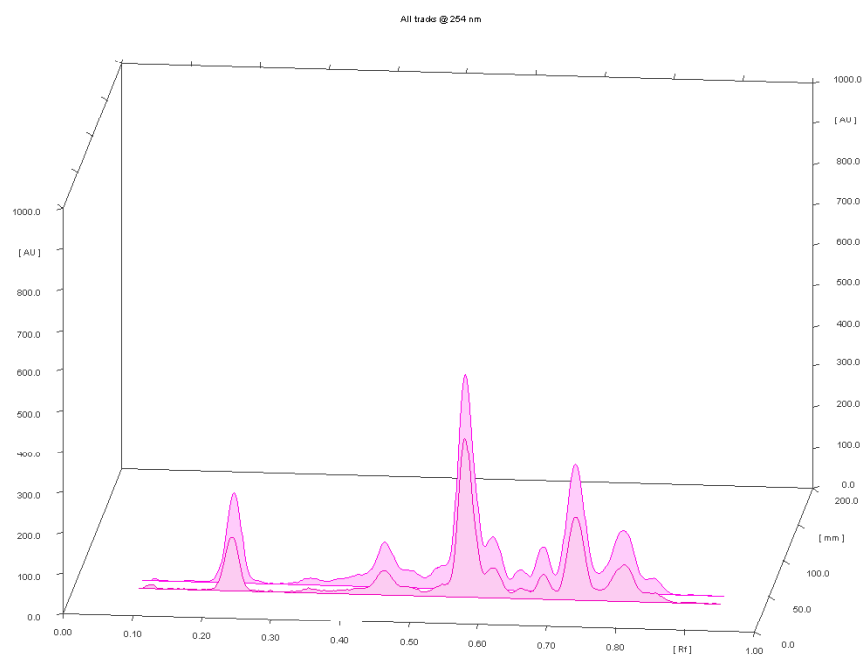
S.NO	PARAMETERS	RESULTS
1.	Aluminium	Present
2.	Magnesium	Present
3.	Iron	Present
4.	Calcium	Present
5.	Starch	Present
6.	Sugar	Present
7.	Tannic acid	Present
8.	Alkaloids	Present

**Table 3. METAL CONTENT (AAS)**

SAMPLE NAME	Fe (ppm)	Zn (ppm)	K (ppm)	Na (ppm)	Ca (ppm)	Mg (ppm)
KUZHPAANDA CHORANAM	0.092	—	NA	—	—	0.135

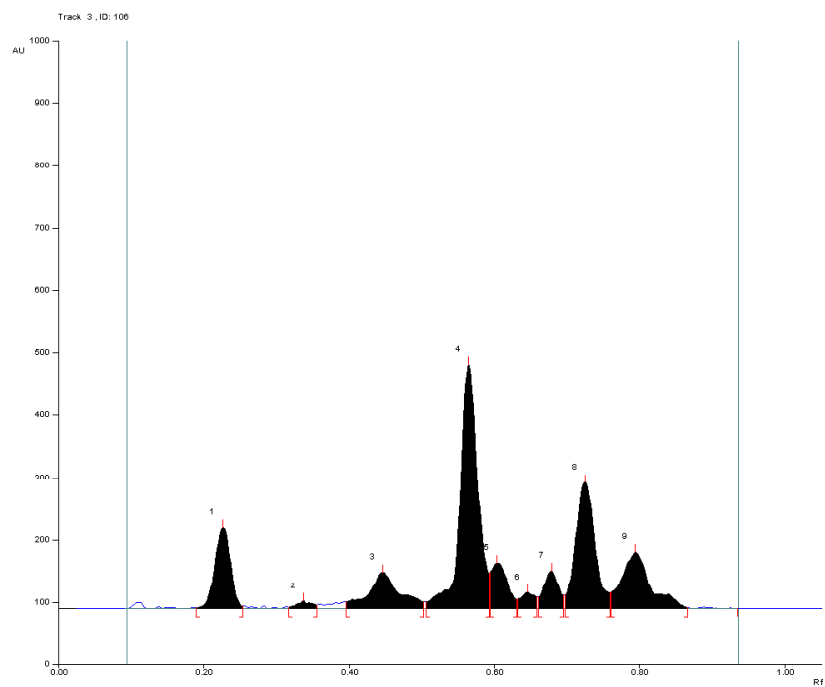
## **106 – HPTLC Profile**

**254nm**

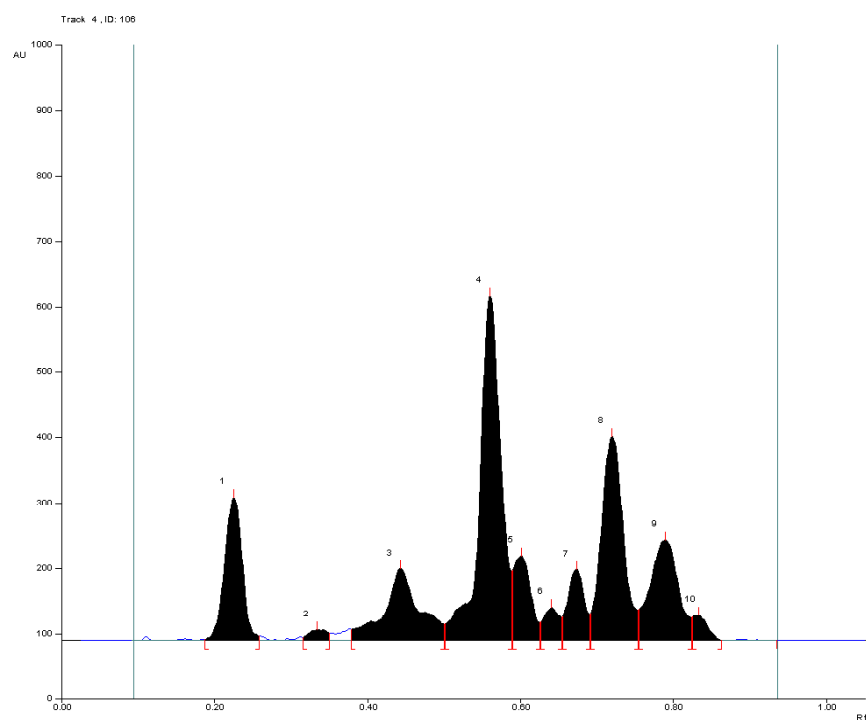


**254nm at 3D Display (Fig No: 106 -01)**



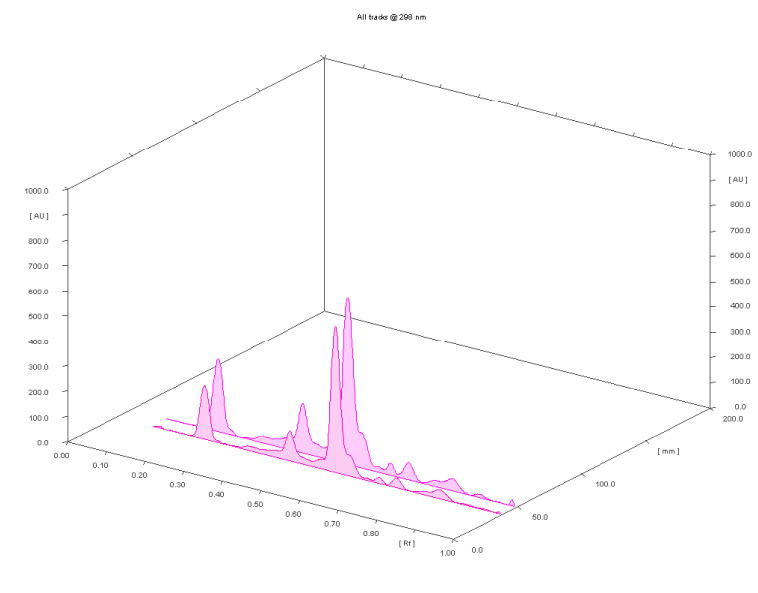


**5µl at 254nm (Fig No: 106 -02)**

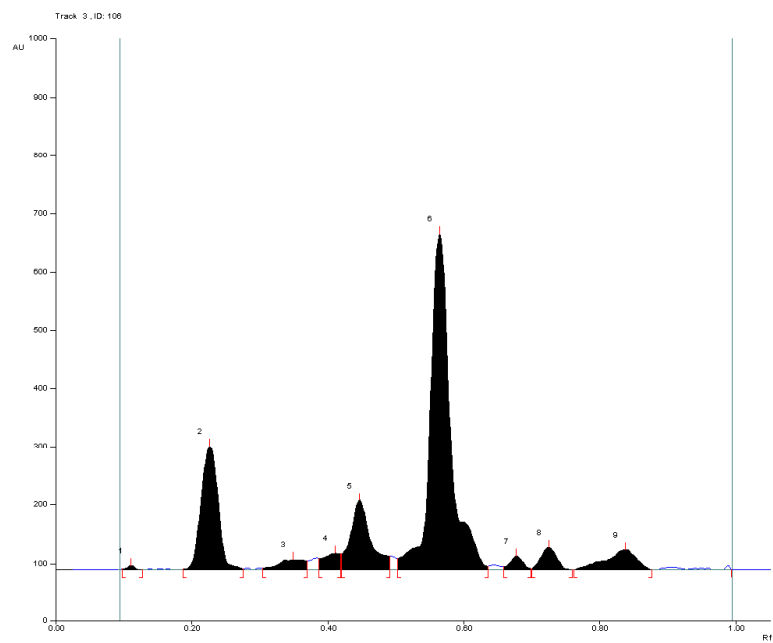


**10 µl at 254nm (Fig No: 106 -03)**

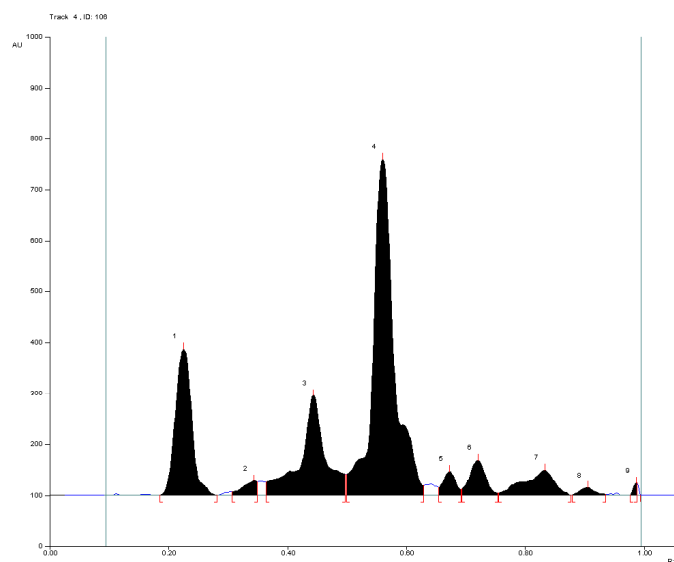
**298nm**



**298 nm at 3D Display (Fig No: 106 -04)**

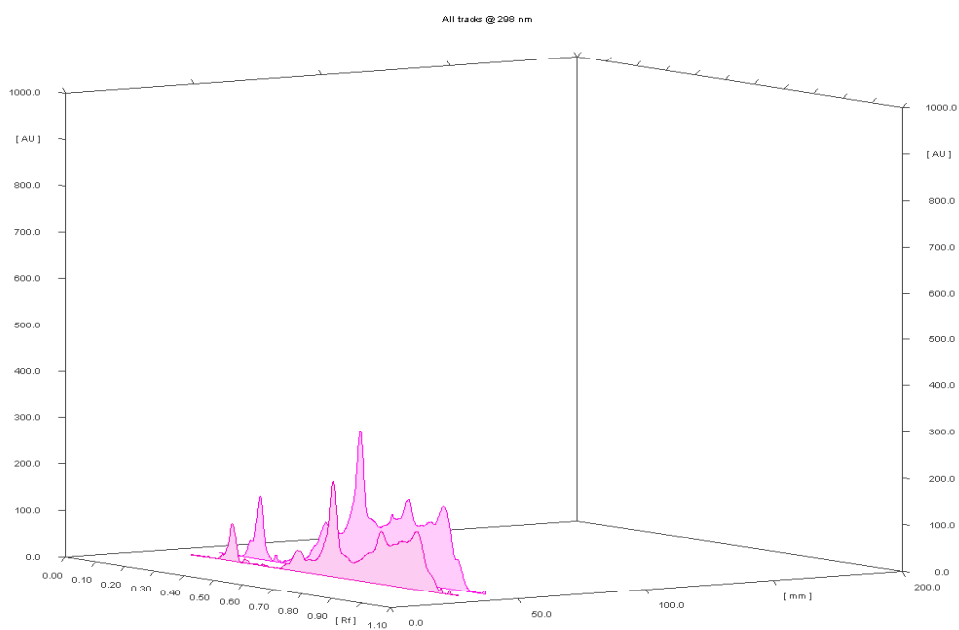


**5µl at 298nm (Fig No: 106 -05)**

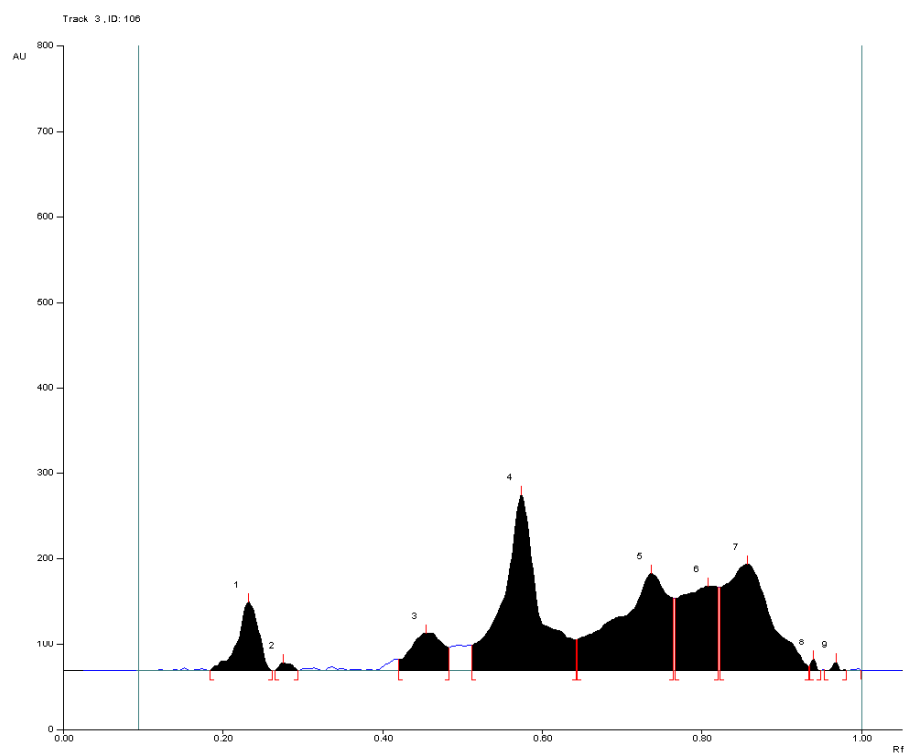


**10µl at 298nm (Fig No: 106 -06)**

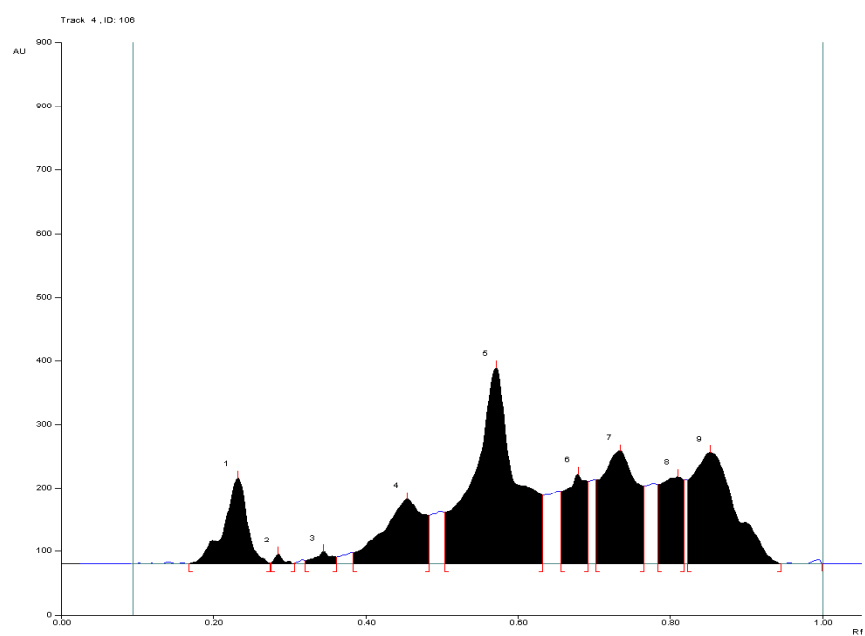
### **Derivatisation (298nm)**



**298 nm at 3D Display\_ (Fig No:106 -07)**

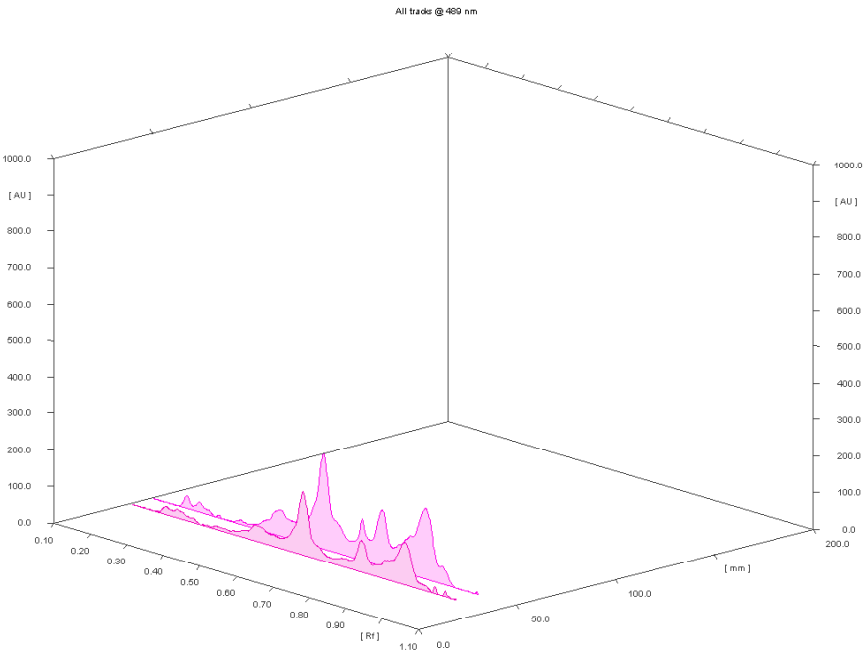


**Derivatisation 5µl at 298nm (Fig No: 106 -08)**

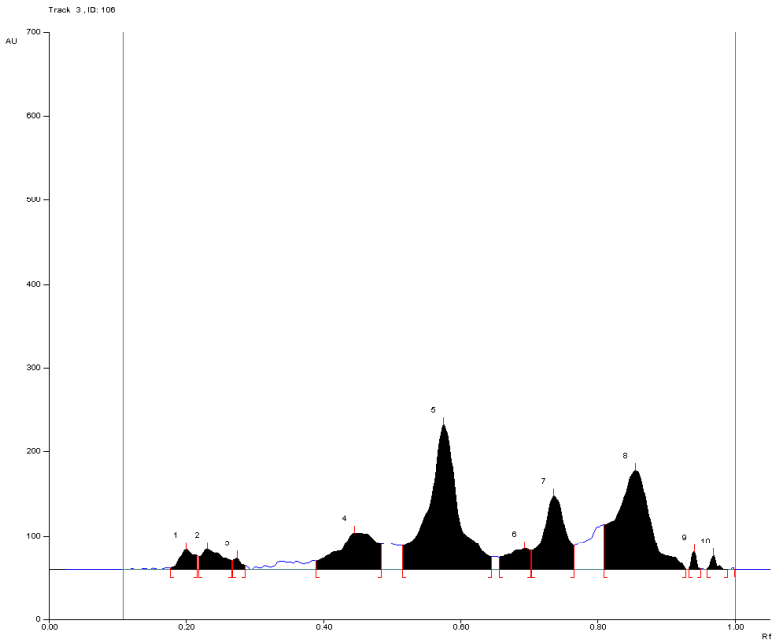


**Derivatisation 10µl at 298nm (Fig No: 106 -09)**

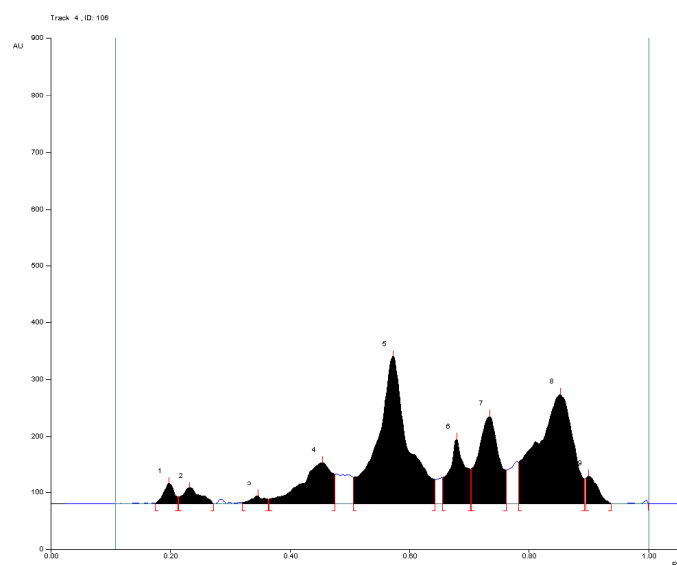
**Derivatisation (498nm)**



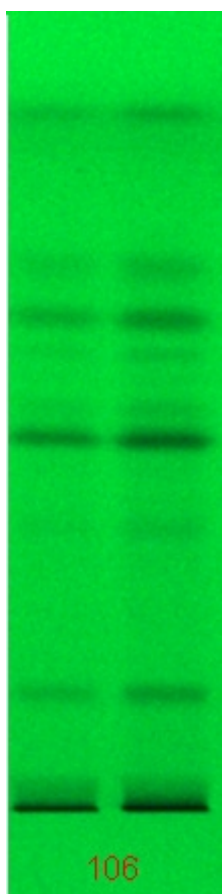
**489 nm at 3D Display (Fig No: 106 -10)**



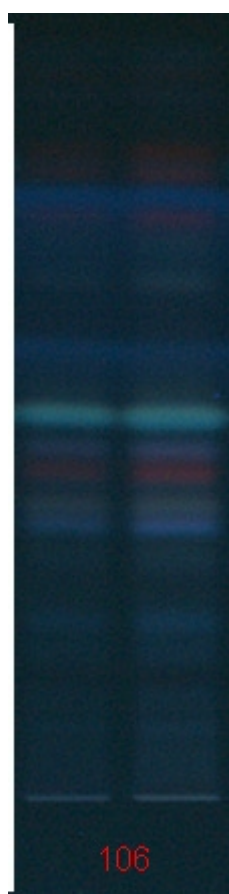
**Derivatisation 5µl at 489nm (Fig No: 106 -11)**



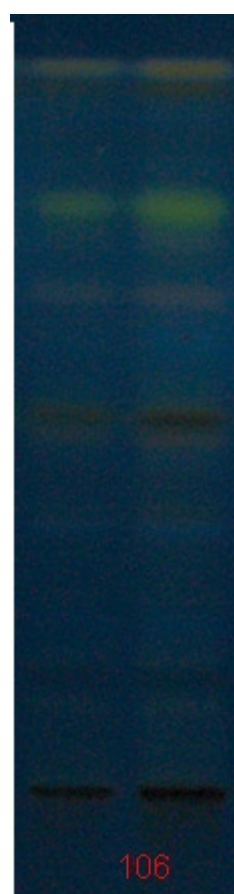
**Derivatisation 10 $\mu$ l at 489nm (Fig No: 106 -12)**



254nm (No: 106 -13)



366nm (No: 106 -14)



366nm (No: 106 -15)



White light (No: 106 -16)

## PHARMACOLOGICAL STUDIES

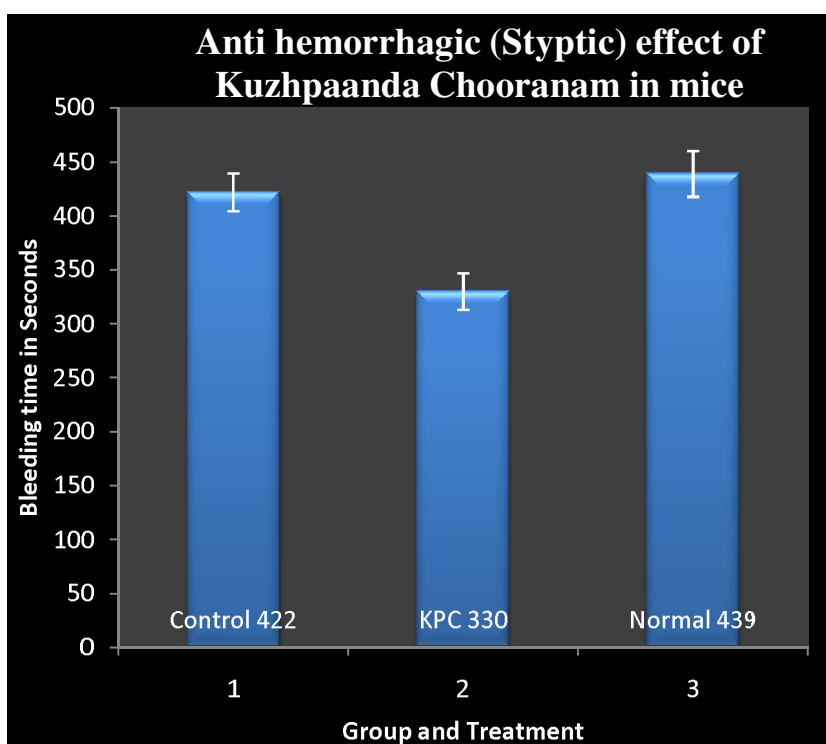
### STYPTIC ACTIVITY OF KUZHPAANDA CHOORANAM

**Table 4. Anti hemorrhagic (Styptic) effect of Kuzhpaanda Chooranam in mice**

S. No.	Group and treatment	Bleeding time in seconds
1.	I- Control-(2ml/kg 2% CMC)	422±17.42
2.	II- Kuzhpaanda Chooranam	330±16.85**
3.	III- Normal control	439±21.23

Values are expressed as mean  $\pm$  S.E.M.; n = 6; \*\*P<0.01 VS Normal and Control

**Fig:1. Anti hemorrhagic (Styptic) effect of Kuzhpaanda Chooranam in mice**



# TOXICITY STUDIES OF KUZHPAANDA CHOORANAM

Table 5. Dose finding experiment and its behavioral Signs of Toxicity

No	Dose mg/kg	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
1	2000	+	+	-	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	5000	+	+	-	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-	+	-

1. Alertness
2. Aggressiveness
3. Pile erection
4. Grooming
5. Gripping
6. Touch Response
7. Decreased Motor Activity
8. Tremors
9. Convulsions
10. Muscle Spasm
11. Catatonia
12. Muscle relaxant
13. Hypnosis
14. Analgesia
15.Lacrimation
16. Exophthalmos
17. Diarrhoea
18. Writting
19. Respiration
20. Mortality

Table 6. Body wt (g) of rats exposed to *Kuzhpaanda Chooranam* for 28days.

Dose (mg/kg/day)	Days		7		14		21		28	
	1									
Control	111.54±5.40		112.32±6.16		114.56±5.20		117.15±4.56		120.02±4.25	
100	115.40±4.28		117.28±5.10		120.10±5.56		123.40±5.15		125.10±4.46	
200	118.02±5.12		118.10±6.45		120.12±5.10		122.01±5.10		124.21±6.10	
400	112.10±5.20		115.44±5.24		117.10±5.02		120.00±4.23		122.10±5.22	

Values are mean ± S.E.M. (Dunnet 't' test). <sup>ns</sup>P>0.05; Vs Control N=6.



**Table 7. Food (g/day) intake of rats exposed to *Kuzhpaanda Chooranam* for 28days.**

Dose (mg/kg/day)	Days (gms/rats)				
	1	7	14	21	28
Control	50.18±2.24	54.48±2.42	56.10±2.46	52.13±2.61	52.04±3.46
100	52.24±2.61	55.23±2.40	48.44±2.60	47.18±2.45	48.98±3.14
200	45.30±2.10	52.25±2.47	47.44±2.45	50.46±2.10	48.46±3.62
400	47.45±2.45	55.45±2.46	49.45±2.75	52.18±2.12	50.64±3.00

Values are mean ± S.E.M. (Dunnett 't' test). <sup>ns</sup>P>0.05; Vs Control N=6.

**Table 8. Water intake of rats exposed to *Kuzhpaanda Chooranam* for 28days.**

Dose (mg/kg/day)	Days(ml/rat)				
	1	7	14	21	28
Control	50.08±2.48	50.46±3.81	52.35±3.11	50.14±3.18	54.45±3.88
100	50.12±2.45	52.20±3.71	50.20±3.12	49.10±3.40	50.65±2.80
200	52.42±2.62	50.45±3.45	50.25±3.42	48.13±2.48	52.48±3.45
400	50.45±3.45	50.46±3.12	55.02±3.62	52.45±3.33	54.64±3.45

Values are mean ± S.E.M. (Dunnett 't' test). <sup>ns</sup>P>0.05; Vs Control N=6.

**Table 9. Hematological parameters after 28days treatment with *Kuzhpaanda Chooranam*.**

Parameter	Control	100 mg/kg	200 mg/kg	400 mg/kg
<b>RBC (mm<sup>3</sup>)</b>	7.12±0.47	7.52±0.40	8.00±0.41	7.48±0.42
<b>HB (%)</b>	14.44±0.28	14.34±0.33	14.88±0.28	14.45±0.38
<b>Leukocyte (x10<sup>6</sup>/mL)</b>	11.4±1.26	10.3±1.28	10.2±1.12	10.5±1.32
<b>Platelets (X10<sup>5</sup>/µl)</b>	1.22±0.12	1.31±0.11	1.34±0.15	1.34±0.12
<b>MCV (g/l)</b>	84.55±4.5	85.24±5.30	86.12±4.22	84.54±5.24
<b>Neutrophil (%)</b>	52.24±3.15	52.10 ±3.2	50.50±3.4	53.00±3.2
<b>Lymphocytes (%)</b>	44.12±1.28	45.10±3.2	45.65±3.2	46.11±3.0
<b>Eosinophil's (%)</b>	5.0±0.4	5.0±0.4	5±0.3	5±0.2
<b>Monocytes (%)</b>	3.0±0.02	3.0±0.3	3.0±0.3	3.0±0.2
<b>Basophils (%)</b>	0±0	0±0	0±0	0±0
<b>ESR(mm)</b>	1±00	1±00	1±00	1±00
<b>PCV</b>	45.12±3.17	44.08±3.10	43.02±3.12	42.14±3.00

Values are mean ± S.E.M. (Dunnet 't' test). <sup>ns</sup>P>0.05; Vs Control N=6.

**Table 10. Effect of treatment with *Kuzhpaanda Chooranam* biochemical parameters.**

Dose (mg/kg)	Control	100 mg/kg	200 mg/kg	400 mg/kg
Total Bilirubin (mg/dL)	0.209±0.05	0.212±0.06	0.218±0.05	0.215±0.04
Bilirubin direct (mg/dL)	0.1±0.04	0.1±0.05	0.1±0.04	0.1±0.05
ALP (U/L)	72.00±2.8	71.12±2.5	68.18±3.0	70.43±2.8
SGOT (U/L)	73.0±2.7	74.20±2.2	72.15±3.2	75.12 ± 2.0
SGPT(U/L)	80.2±3.3	82.11±4.2	83.25±2.7	79.10±2.5
Total Protein(g/dl)	10.02±1.30	9.17±0.30	8.52±0.27	9.12±0.46
Albumin(g/dl)	3.21±0.25	3.19±0.24	3.46±0.33	3.22±0.12
Globulin(g/dl)	6.02±0.18	5.18±0.26	4.98±0.21*	4.86±0.30**
Urea (mg/dL)	55.42±1.63	54.34±3.56	55.2±2.14	53.88±1.36
Creatinine (mg/dL)	29.45±3.2	30.77±3.0	28.82±3.10	27.25 ± 4.2
Uric acid (mg/dL)	1.6±0.12	1.6±0.18	1.6±0.16	1.6±0.14
Na m.mol	141.10±4.23	141.4±3.22	142.12±4.20	141.14±3.88
K m.mol	20.00±2.02	19.88±2.81	20.33±2.32	20.41±2.34
Cl m.mol	102.45±5.10	101.74±5.24	100.46±4.99	101.34±5.02

Values are mean ± S.E.M. (Dunnet't test). \*P<0.05; \*\*P<0.01. Vs Control

**Table-11. Lipid Profile**

<b>Dose (mg/kg)</b>	<b>Control</b>	<b>100 mg/kg</b>	<b>200 mg/kg</b>	<b>400 mg/kg</b>
<b>Total cholesterol (mg/dL)</b>	40.25±2.33	41.13±2.74	40.10±3.44	42.00±3.00
<b>HDL(mg/dL)</b>	13.20±2.44	13.28±1.70	13.02±1.45	14.20±2.12
<b>LDL(mg/dL)</b>	42.18±2.46	42.00±3.12	42.74±3.40	43.13±3.22
<b>VLDL(mg/dl)</b>	16.77±2.74	15.64±2.17	16.27±1.54	15.40±1.21
<b>Triglycerides (mg/dl)</b>	86.20±3.00	85.12±2.88	84.40±3.00	85.10±2.64
<b>Blood glucose(mg/dl)</b>	125.11±3.99	126.41±4.01	124.02±4.00	125.40±2.22

Values are mean ± S.E.M. (Dunnett 't' test). <sup>ns</sup>P>0.05; Vs Control N=6.

Table 12. Urine Analysis

Parameters	Control	100 mg/kg	200 mg/kg	400 mg/kg
<b>Colour</b>	Yellow	Yellow	Yellow	Yellow
<b>Transparency</b>	Clear	Slightly turbid	Slightly cloudy	Slightly turbid
<b>Specific gravity</b>	1.010	1.010	1.010	1.010
<b>PH</b>	>7.2	>8.0	>8.0	>9.0
<b>Protein</b>	Nil	3+	3+	3+
<b>Glucose</b>	Nil	Nil	Nil	Nil
<b>Bilirubin</b>	-ve	-ve	-ve	-ve
<b>Ketones</b>	-ve	+ve	+ve	+ve
<b>Blood</b>	Absent	Absent	Absent	Absent
<b>Urobilinogen</b>	Normal	Abnormal	Abnormal	Abnormal
<b>Pus cells</b>	0-cells/HPF	1-cell/HPF	2-cells/HPF	1-cell/HPF
<b>RBCs</b>	Nil	Nil	0-1cells/HPF	Nil
<b>Epithelial cells</b>	Nil	1-cell/HPF	Nil	1-cell/HPF
<b>Crystals</b>	Nil	Nil	Nil	Nil
<b>Casts</b>	Nil	Nil	Nil	Nil
<b>Others</b>	Bacteria seen	Bacteria seen	Bacteria seen	Bacteria seen

**Table 13. Effect of *Kuzhpaanda Chooranam* on organ weight**

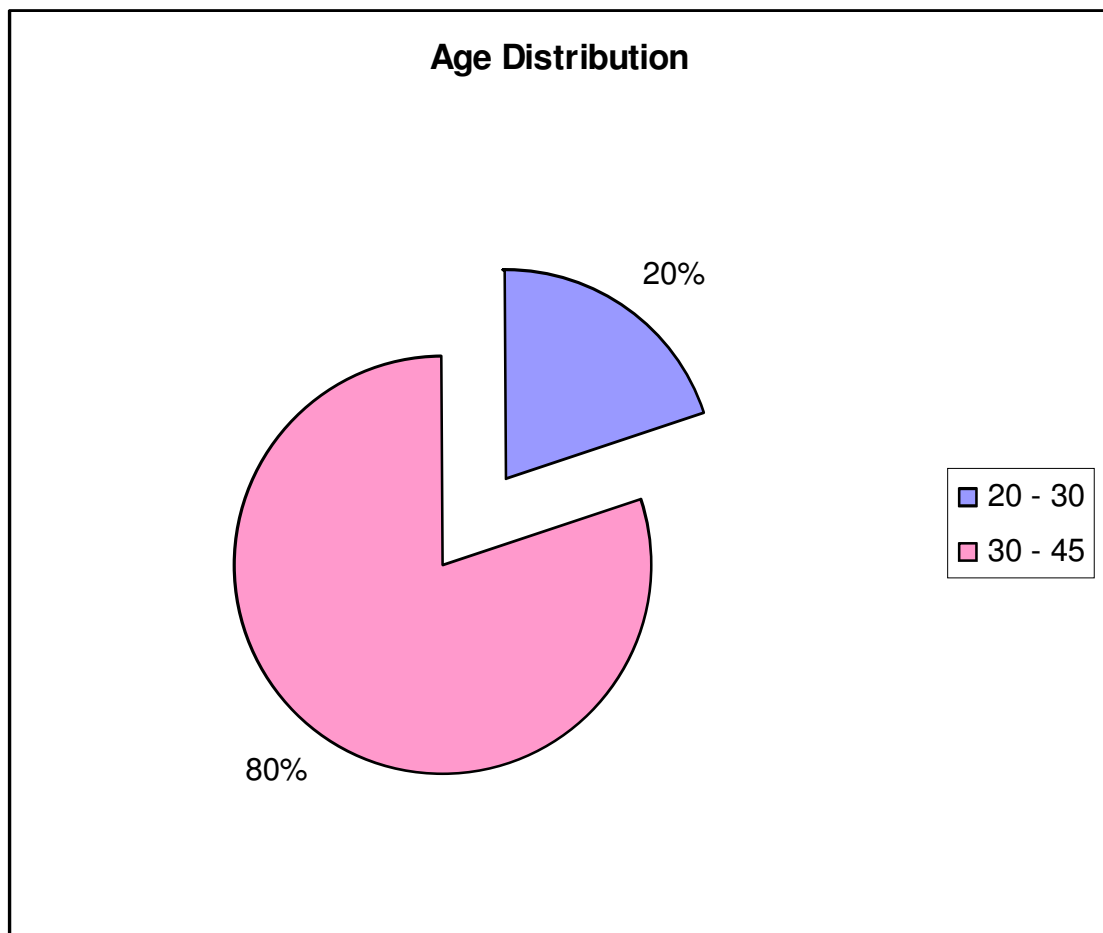
<b>Dose (mg/kg)</b>	<b>Control</b>	<b>100 mg/kg</b>	<b>200 mg/kg</b>	<b>400 mg/kg</b>
<b>Liver (g)</b>	7.12±0.15	6.88±0.15	6.92±0.12	6.12±0.18
<b>Heart (g)</b>	0.62±0.05	0.61±0.05	0.60±0.04	0.68±0.04
<b>Lung (g)</b>	1.42±0.18	1.44±0.17	1.38±0.14	1.42±0.15
<b>Spleen (g)</b>	0.68±0.05	0.67±0.04	0.66±0.04	0.67±0.05
<b>Ovary (g)</b>	1.68±0.14	1.70±0.15	1.65±0.14	1.70±0.15
<b>Testes (g)</b>	1.42±0.10	1.44±0.14	1.46±0.12	1.47±0.15
<b>Brain (g)</b>	1.58±0.15	1.58±0.12	1.56±0.10	1.55±0.14
<b>Kidney (g)</b>	0.72±0.08	0.71±0.04	0.72±0.04	0.70±0.05
<b>Stomach (g)</b>	1.30±0.12	1.32±0.10	1.32±0.11	1.34±0.12

Values are mean ± S.E.M. (Dunnet 't' test). <sup>ns</sup>P>0.05; Vs Control N=6.

## PERUMBADU

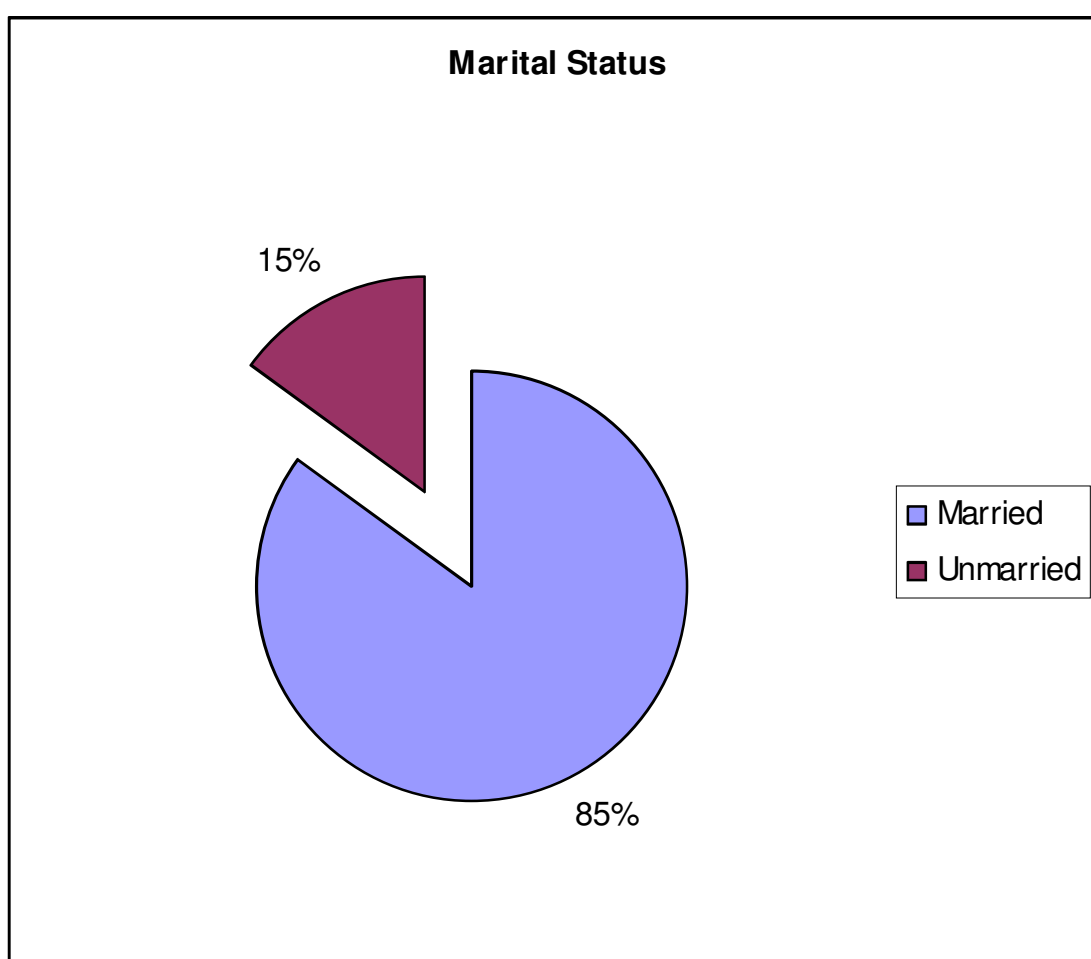
### AGE DISTRIBUTION

SNO	AGE	No of Patients	Percentage
1	20 - 30	4	20%
2	30 - 45	16	80%



## MARITAL STATUS

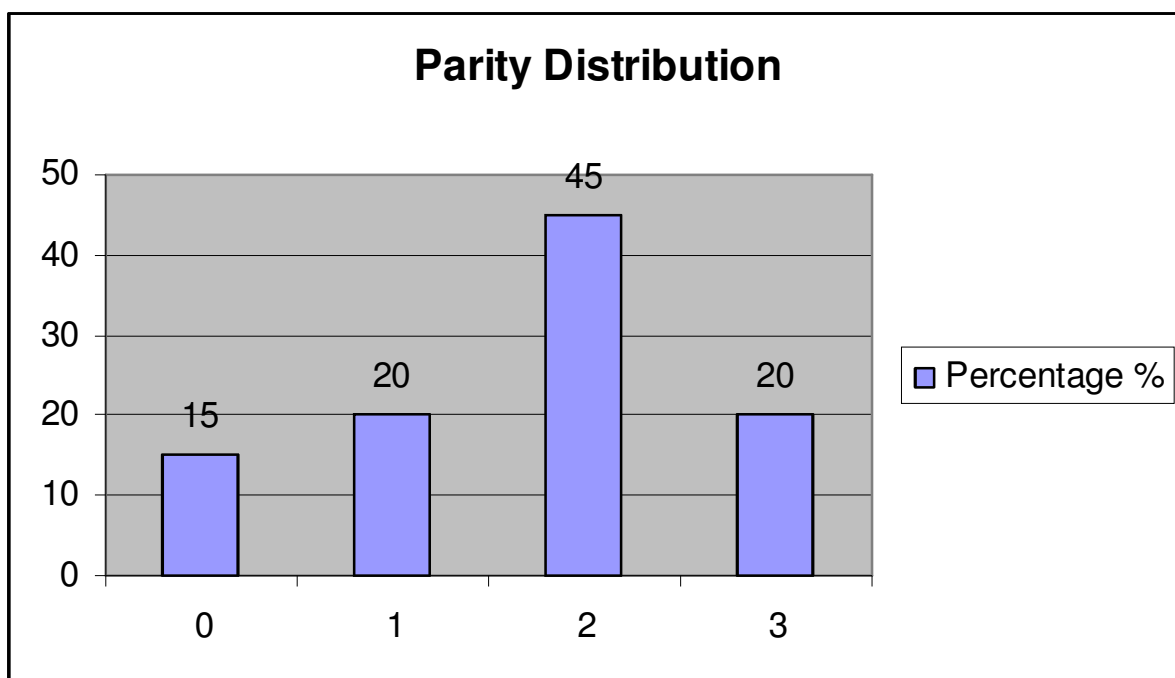
S.No	Marital Status	No of Patients	Percentage
1	Married	17	85%
2	Unmarried	3	15%





## PARITY DISTRIBUTION

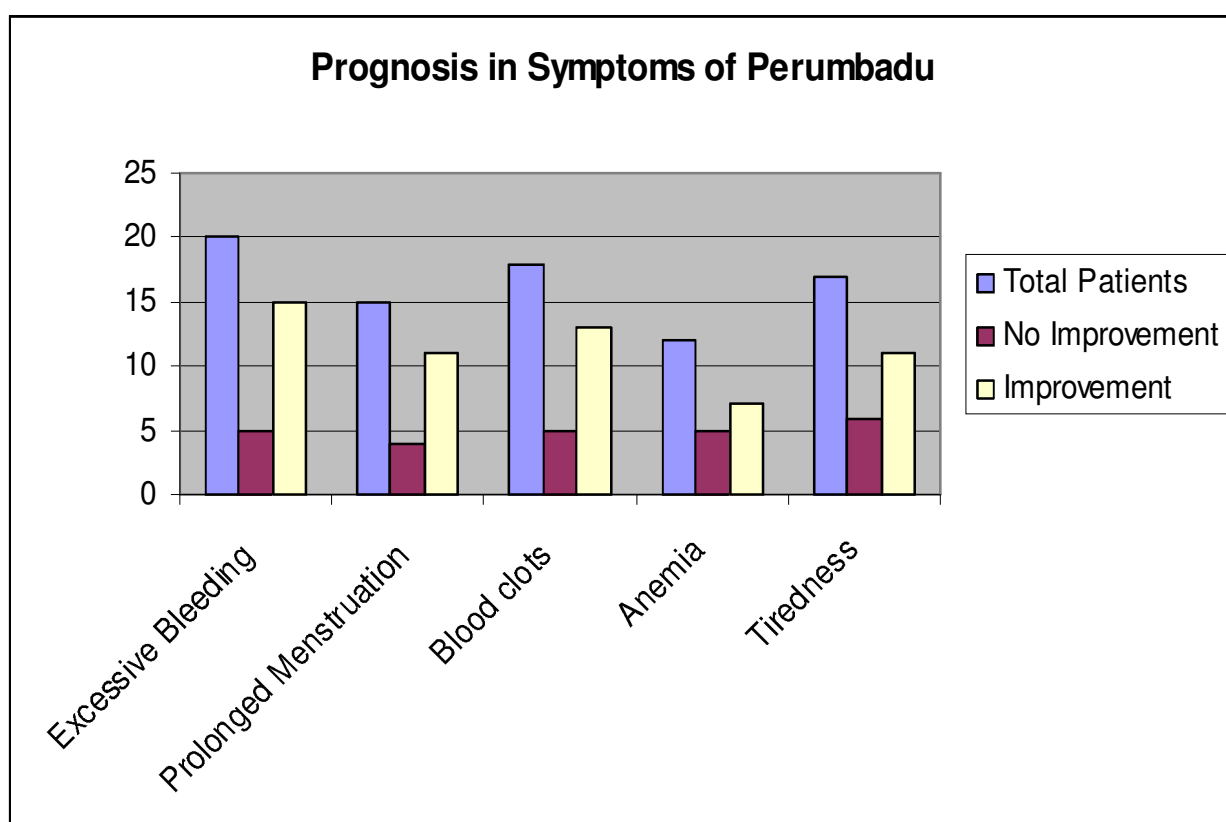
Sno	Parity	No of Patients	Percentage %
1	0	3	15
2	1	4	20
3	2	9	45
4	3	4	20



## PROGNOSIS IN SYMPTOMS OF PERUMBADU

**Table 14. PROGNOSIS IN SYMPTOMS OF PERUMBADU**

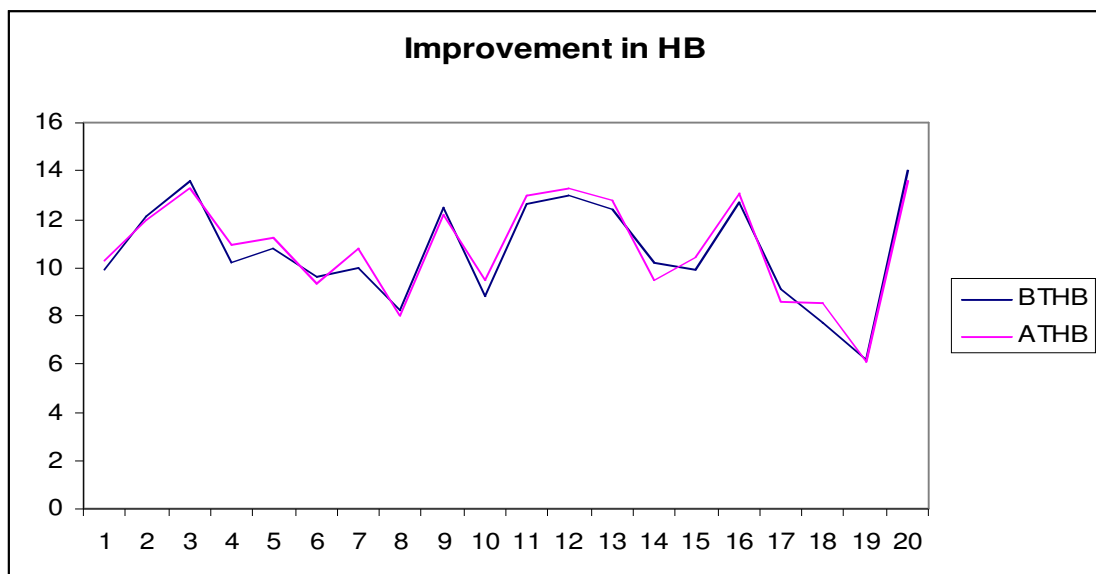
Sno	Symptoms	No of Patients before Treatment	No of Patients After Treatment		Percentage Improvement
			No Improvement	Improvement	
1	Excessive Bleeding	20	5	15	75%
2	Prolonged Menstruation	15	4	11	73%
3	Blood clots	18	5	13	72%
4	Anemia	12	5	7	58%
5	Tiredness	17	6	11	65%



Improvement in Haemoglobin Level

**Table 15. Improvement in Haemoglobin Level**

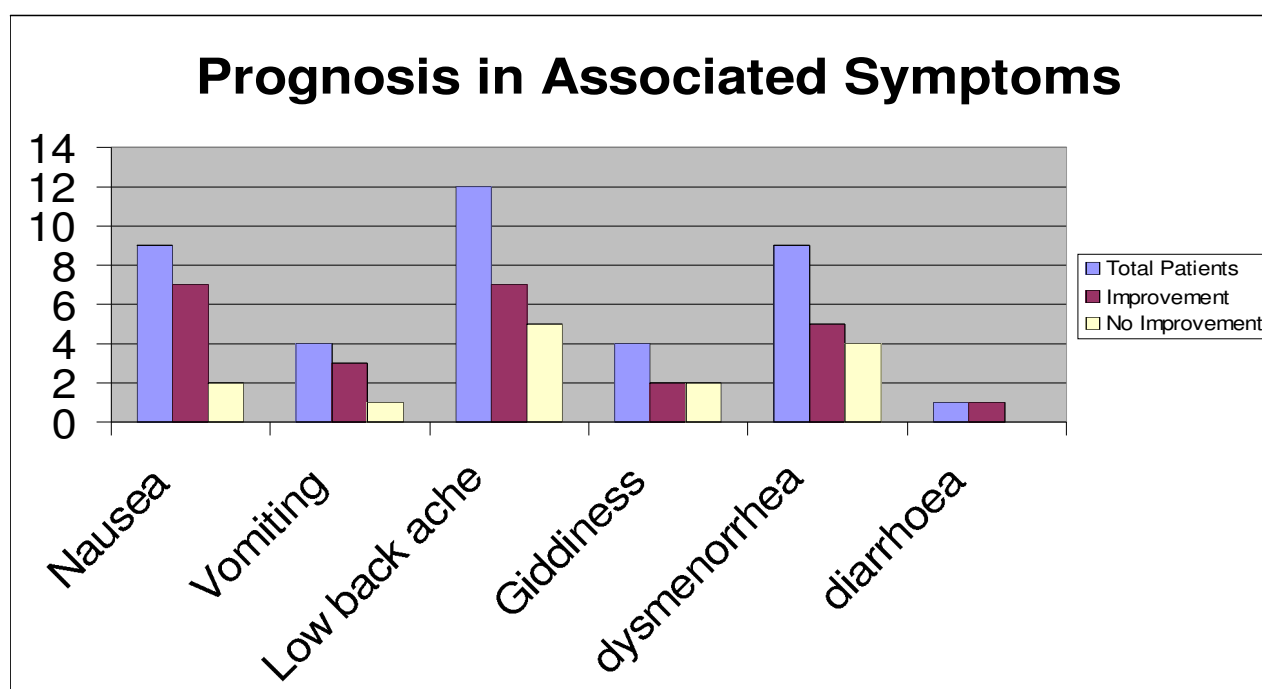
Sno	OPD No	BTHB	ATHB
1	C81030	9.9	10.3
2	C82464	12.1	12
3	C82460	13.6	13.3
4	C17809	10.2	10.9
5	C83237	10.8	11.2
6	C87244	9.6	9.3
7	C73593	10	10.8
8	C86579	8.2	8
9	C86601	12.5	12.2
10	C66444	8.8	9.5
11	C89082	12.6	13
12	C91392	13	13.3
13	C92081	12.4	12.8
14	C099797	10.2	9.5
15	D003293	9.9	10.4
16	C30634	12.7	13.1
17	C97666	9.1	8.6
18	C88057	7.7	8.5
19	C95465	6.2	6.1
20	D003293	14	13.6



## IMPROVEMENT IN THE OTHER ASSOCIATED SYMPTOMS OF THE PERUMBADU PATIENTS

**Table 16. Improvement in other associated symptoms**

S.NO.	Symptoms	Before treatment	After treatment		Improvement %
			Improvement	No improvement	
1	Nausea	9	7	2	77.78%
2	Vomiting	4	3	1	75.00%
3	Low back ache	12	7	5	58.33%
4	Giddiness	4	2	2	50.00%
5	Dysmenorrhoea	9	5	4	55.56%
6	Diarrhea	1	1	0	100.00%



## Improvement in Symptoms:

### Table 17. Improvement in symptoms

Sno	Opd No	Name	Age	Sex	BTEB	ATEB	BTPM	ATPM	BTBC	ATBC	BTA	ATA	BTT	ATT
1	C81030	M.Thilagavathy	40	F	+	-	+	-	+	-	+	-	+	-
2	C82464	Eshwari	37	F	+	-	+	+	+	-	-	-	+	+
3	C82460	Muniamma	40	F	+	-	+	-	+	-	-	-	+	-
4	C17809	Kalaivani	34	F	+	-	-	-	+	+	+	-	+	-
5	C83237	Aarifa	35	F	+	-	+	-	+	-	+	-	+	+
6	C87244	Kalaiselvi	45	F	+	+	+	-	-	-	+	+	+	-
7	C73593	Ramani	45	F	+	-	-	-	-	-	+	-	+	-
8	C86579	Bala	20	F	+	-	+	-	+	-	+	+	+	-
9	C86601	S.Thilagavathy	26	F	+	-	-	-	+	+	-	-	+	-
10	C66444	M.Saranya	20	F	+	-	+	-	+	-	+	-	+	+
11	C89082	Sujatha	45	F	+	+	+	+	+	-	-	-	+	-
12	C91392	E. Saranya	23	F	+	-	+	+	+	-	-	-	+	-
13	C92081	Mahalakshmi	35	F	+	-	-	-	+	+	-	-	+	-
14	C099797	Shanthi	35	F	+	+	+	-	+	-	+	+	-	-
15	D003293	Banu	45	F	+	-	+	+	+	-	+	-	+	-
16	C30634	Mohana	42	F	+	-	-	-	+	-	-	-	+	-
17	C97666	Veeramal	43	F	+	+	+	-	+	-	+	+	-	-
18	C88057	Renuka	35	F	+	-	+	-	+	+	+	-	+	-
19	C95465	Kanaagi	40	F	+	+	+	-	+	-	+	+	-	-
20	D003293	Kathija	44	F	+	-	+	-	+	+	-	-	+	+
BT-before treatment			AT-after treatment			EB-excessive bleeding			PM-prolonged menstruation					
BC-blood clots			A-anemia			T-tiredness								



**Table 19. Investigation before treatment**

SN O	OPD NO	NAME	TC	DC			TRB C	ESR		PLT	CT	BLOOD SUGAR		SG OT	SG PT	UR ALP	UR EA	CREATININE	TOTAL CHOLESTROL	TOTAL PROTEIN M	CALCIU M	PHOS PHOR OUS	URINE		URINE DEPOSITS		
				P	L	E		1/2 hrs	1 hr			F	PP										Alb	Sug ar		Pus Cells	Epi Cells
1	C81030	M.Thilagavathy	8300	40	53	7	4.2	4	10	3.3	2.2	3.3	86	121	44	35	132	15	0.5	196	6.2	9	3.2	NIL	NIL	2-3	3-4
2	C82464	Eshwari	8500	53	43	4	4.3	6	10	4.4	2	3.3	92	132	46	35	120	16	0.5	175	6.1	9.6	3.5	NIL	NIL	2-4	1-2
3	C82460	Muniamma	9000	52	42	5	4	2	4	2.9	2	4	101	119	25	26	198	26	0.7	160	7.1	10.6	2.8	NIL	NIL	2-3	1-2
4	C17809	Kalaivani	8300	61	32	6	3.9	14	30	2.6	2.3	4	99	111	25	27	124	17	0.6	132	7.2	10	4.9	NIL	NIL	2-4	3-5
5	C83237	Aarifa	9000	70	25	5	3.8	10	24	4.3	2	4.3	103	136	20	22	159	16	0.5	172	6.9	9.3	3	NIL	NIL	1-2	2-3
6	C87244	Kalaiselvi	8200	55	39	6	4.2	2	4	3.2	1	3.2	96	124	43	44	230	22	0.6	180	7.3	11.9	2.8	NIL	NIL	2-4	2-4
7	C73593	Ramani	8700	70	23	6	4.8	12	30	2.9	2.3	4.3	104	149	111	14	136	14	0.4	201	7	10	3.3	NIL	NIL	2-3	3-5
8	C86579	Bala	8800	62	33	5	4	12	40	3.2	2	4.3	92	120	10	13	160	16	0.6	184	6.2	10.8	4.2	NIL	NIL	1-2	2-3
9	C86601	S.Thilagavathy	8900	60	36	4	4.5	18	38	5	3	4.15	109	121	16	17	150	14	0.4	159	7.1	11.6	3.2	NIL	NIL	2-3	2-3
10	C66444	M.Saranya	8900	69	22	6	4.3	6	14	3.4	2.3	4	112	132	16	17	165	24	0.7	145	7	10.6	2.8	NIL	NIL	2-4	2-4
11	C89082	Sujatha	9400	63	31	6	3.8	4	10	4.3	2	4	82	122	30	28	162	19	0.6	220	6.8	11.4	3	NIL	NIL	2-3	2-3
12	C91392	E. Saranya	6800	52	40	6	4.4	20	42	2	3.3	4.15	115	122	24	26	160	23	0.7	163	6.9	11	2.5	NIL	NIL	1-2	2-3
13	C92081	Mahalakshmi	6400	67	26	5	4.1	6	20	2.9	2.3	3	103	128	15	16	146	16	0.7	148	7.7	11.2	4.5	NIL	NIL	2-3	2-3
14	C099797	Shanthi	6200	60	33	7	4.1	2	4	3.1	2	3.15	117	123	12	14	149	14	0.4	209	7.5	11	3.9	NIL	NIL	3-5	3-5
15	D003293	Baru	8700	62	36	2	4.7	20	40	3.9	1.3	4	100	118	17	19	152	17	0.5	140	5.8	11.5	4	NIL	NIL	1-2	1-2
16	C30634	Mohana	9000	56	40	4	3.9	6	18	3.1	3	4.15	111	138	20	21	146	15	0.4	192	5	10.9	2.8	NIL	NIL	3-4	1-2
17	C97666	Veeramal	6800	50	45	5	4.9	12	32	2.5	2	4	92	116	14	16	152	14	0.4	157	6.6	11.2	2.6	NIL	NIL	1-2	1-3
18	C88057	Renuka	6900	47	49	4	3.8	16	34	3.1	2.3	4.2	95	109	16	18	154	28	0.9	124	6.7	11.5	3.2	NIL	NIL	1-2	2-3
19	C95465	Kannagi	6200	65	30	5	3.7	6	20	3.3	2	3	100	120	12	14	167	14	0.4	187	6.6	11.2	4.5	NIL	NIL	1-2	2-4
20	D003293	Kathija	8800	60	35	5	4.1	4	8	3.3	2.3	4	113	129	12	14	166	15	0.6	154	7	10.8	3	NIL	NIL	3-4	4-5

**Table 20. Investigation after treatment**

SN O	OPD NO	NAME	AGE	SEX	HB	TC	DC			ESR		PLT		BT	CT	BLOOD			SG	PT	ALP	UREA	CREATININE	TOTAL CHOLESTROL	TOTAL PROTEIN	CALCIUM	PHOSPHOROUS	URINE		Epi Cells	
							P	L	E	TRB C	1/2 hrs	1hr	F			PP	OT	Albu min										Sug ar			
1	C81030	M.Thilagavathy	40	F	10.3	8200	45	49	6	4.3	4	10	3.2	2.1	3.2	89	132	49	36	135	20			6.3		10	2.9	NIL	NIL	2-3	3-4
2	C82464	Eshwari	37	F	12	8400	53	43	4	4.3	8	8	4.3	2.1	3.1	100	125	44	35	132	17			6.2		9.7	3.4	NIL	NIL	2-3	2-3
3	C82460	Muniamma	40	F	13.3	8900	59	36	5	4.2	6	8	2.8	2.2	4	110	120	20	27	185	25			7.4		10.5	3.2	NIL	NIL	1-2	1-2
4	C17809	Kalaivani	34	F	10.9	8200	60	36	4	4.1	12	24	2.5	2.1	4	115	125	26	29	130	23			7.1		10.2	2.8	NIL	NIL	1-2	3-4
5	C83237	Aarifa	35	F	11.2	8700	52	45	3	3.7	8	22	4.2	2	4.2	119	140	27	20	158	22			7		9.4	4.2	NIL	NIL	2-4	1-2
6	C87244	Kalaiselvi	45	F	9.3	8500	48	47	5	4.1	4	6	3.1	2	3.1	85	115	35	43	222	19			7.2		11.5	3.2	NIL	NIL	2-3	2-3
7	C73593	Ramani	45	F	10.8	8600	56	40	4	4.5	10	18	2.6	2.2	4.1	114	132	90	17	126	16			7.1		9.5	3.2	NIL	NIL	2-4	3-4
8	C86579	Bala	20	F	8	8900	55	40	5	3.9	8	28	3.1	2.3	4.2	95	101	19	15	150	14			6.4		10.5	3.4	NIL	NIL	2-3	1-2
9	C86601	S.Thilagavathy	26	F	12.2	9000	49	45	6	4.3	16	26	5.2	3.1	4.1	86	110	25	19	140	19			7		11.2	3.5	NIL	NIL	1-2	1-2
10	C66444	M.Saranya	20	F	9.5	8700	47	48	5	4.4	6	12	3.3	2.2	3.9	114	122	16	20	170	23			7.2		10.3	2.9	NIL	NIL	2-3	2-3
11	C89082	Sujatha	45	F	13	9500	42	53	5	3.9	4	8	4.2	2.1	4.2	84	142	17	27	165	22			6.5		11.2	3	NIL	NIL	2-4	1-3
12	C91392	E. Saranya	23	F	13.3	6900	45	51	4	4.3	12	32	2.3	3.2	4	105	112	15	25	155	25			6.7		11	3.2	NIL	NIL	2-3	1-3
13	C92081	Mahalakshmi	35	F	12.8	6300	43	55	2	4.2	8	18	2.7	2.2	3.2	95	118	20	17	150	29			7.6		11.5	4.3	NIL	NIL	1-2	2-4
14	C099797	Shanthi	35	F	9.5	6100	42	55	3	4.3	4	6	3.3	2.2	3.3	106	120	25	16	165	17			7.7		11.1	2.6	NIL	NIL	3-4	3-5
15	D003293	Banu	45	F	10.4	8900	52	42	6	4.6	16	28	3.8	1.2	4.2	97	110	19	21	132	15			5.5		11.2	3.4	NIL	NIL	1-2	1-2
16	C30634	Mohana	42	F	13.1	9200	41	55	4	4.2	8	16	3.5	3.1	4.2	86	103	18	25	156	18			5.9		10.9	2.9	NIL	NIL	2-4	2-4
17	C97666	Veeramal	43	F	8.6	6500	40	55	5	4.2	8	28	2.7	2.1	3.8	93	110	14	19	142	17			6.3		11.2	3.7	NIL	NIL	3-5	2-3
18	C88057	Renuka	35	F	8.5	6300	53	42	5	3.7	14	32	3.4	2.2	4.1	100	114	15	14	164	21			6.8		9.7	3.5	NIL	NIL	1-2	2-3
19	C95465	Kannagi	40	F	6.1	5900	46	50	4	3.6	8	18	3.2	2.1	2.9	102	112	17	18	157	22			6		9.8	3.1	NIL	NIL	3-4	2-4
20	D003293	Kathija	44	F	13.6	8700	50	46	4	4.2	6	10	3.5	2.2	3.9	96	115	16	15	153	17			7.1		10.3	2.9	NIL	NIL	2-3	1-2



## Statistical Analysis

All collected data were entered into MS Excel software using different columns as variables and rows as patients. SPSS software was used to perform statistical analysis. Basic descriptive statistics include frequency distributions and cross-tabulations were performed. The quantity variables were expressed as Mean  $\pm$  Standard Deviation and qualitative data as percentage. A probability value of  $<0.05$  was considered to indicate as statistical significance. Paired 't' test was performed for determining the significance between before and after treatment.

### PERUMBADU (MENORRHAGIA)

**Table 21. Paired t test for Symptoms before and after treatment:**

Variable	Obs	Mean	Std.dev	t.value	P value
Before symptoms	20	4.05	0.686	12.704	P<0.0001
After symptoms	20	1.15	0.745		

For symptoms, Mean $\pm$ Standard deviation before treatment is 4.05 and after treatment is 1.15 which is statistically significant ( $p<0.0001$ ).

**Table 22. Paired t test for Hb before and after treatment:**

Variable	Obs	Mean	Std.dev	t.value	P value
Before symptoms	20	10.675	2.1205	-1.378	0.184
After symptoms	20	10.820	2.1045		

For Hb, Mean $\pm$ Standard deviation before treatment is 10.675 and after treatment is 10.820 which is significant ( $p=0.184$ ).

## ERAIPPU MATHIRAI

**Table 23. Physical Properties**

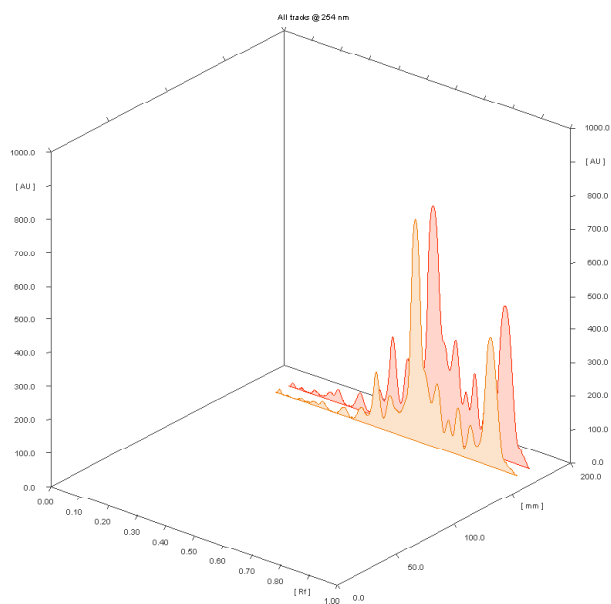
S.No	Characteristic test	Results
1.	pH	5.21
3.	Ash value	0.95 (g/g of Sample)
4	Water soluble ash	0.02 (g/g of Sample)
5	Acid insoluble ash	0.05 (g/g of Sample)

**Table 24. Qualitative Analysis**

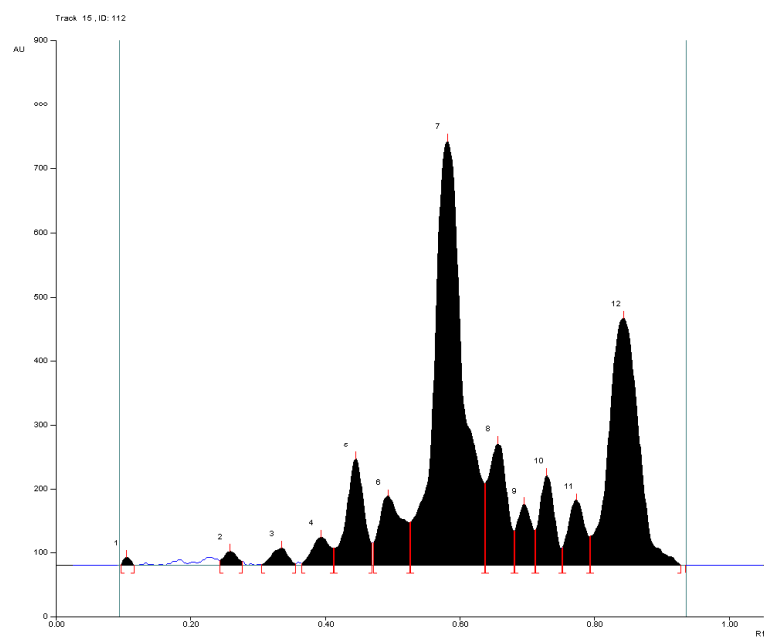
S.No	Parameters	Result
1	Iron	Present
2	Alkaloids	Present

## 112 – HPTLC Profile

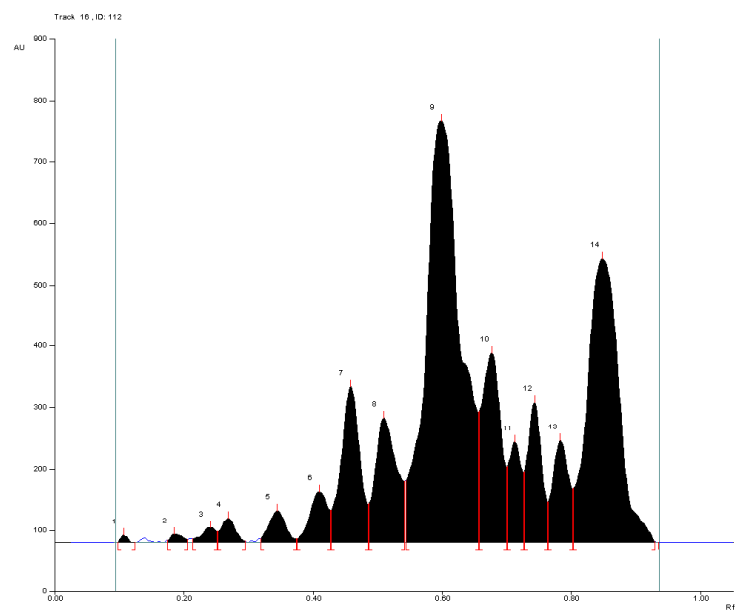
**254nm**



**254nm 3D display (No: 112 -01)**

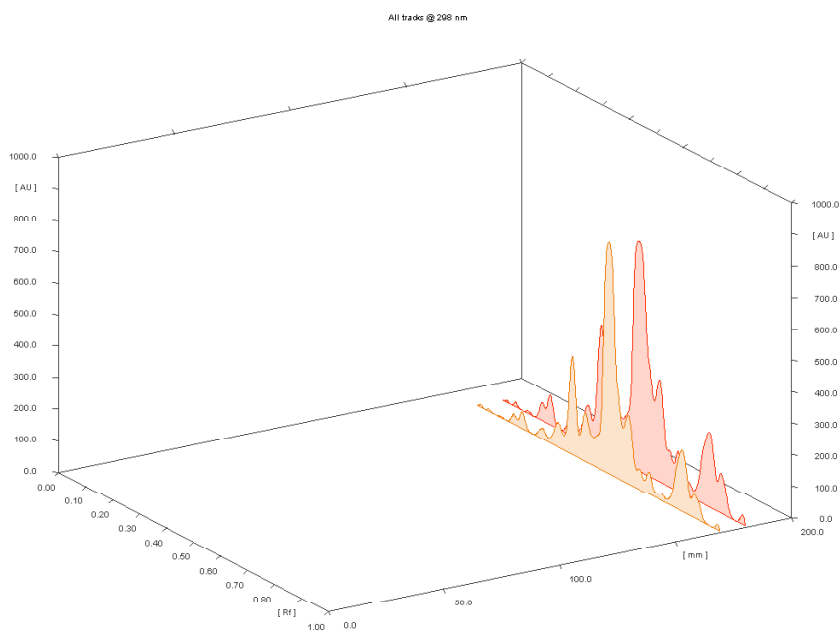


**5µl (254nm) (No: 112 -02)**

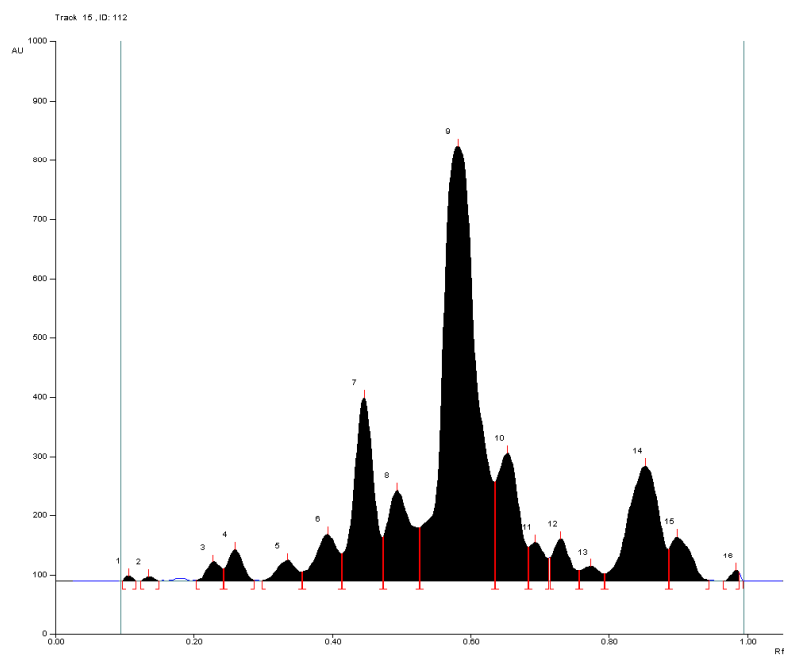


**10  $\mu$ l (254nm) (No: 112 -03 )**

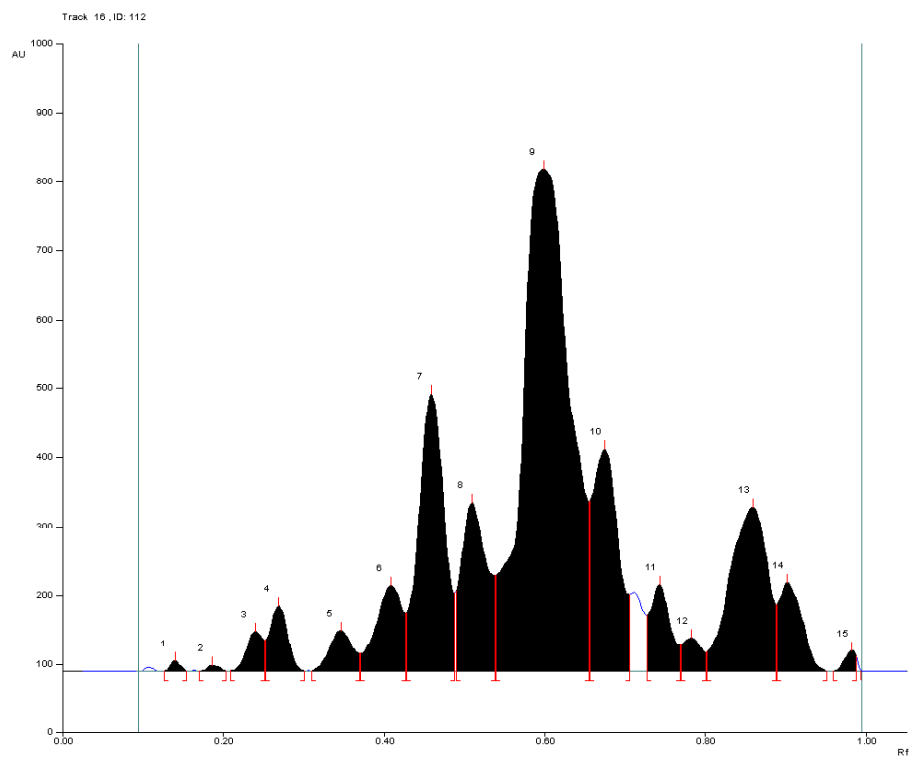
**298nm**



**298 nm 3D display (No: 112 -04 )**

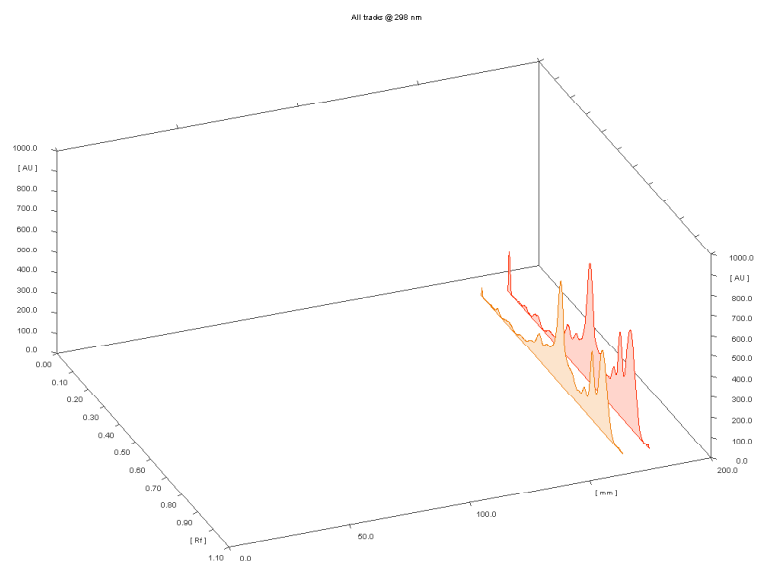


**5 $\mu$ l (298nm) (No: 112 -05 )**

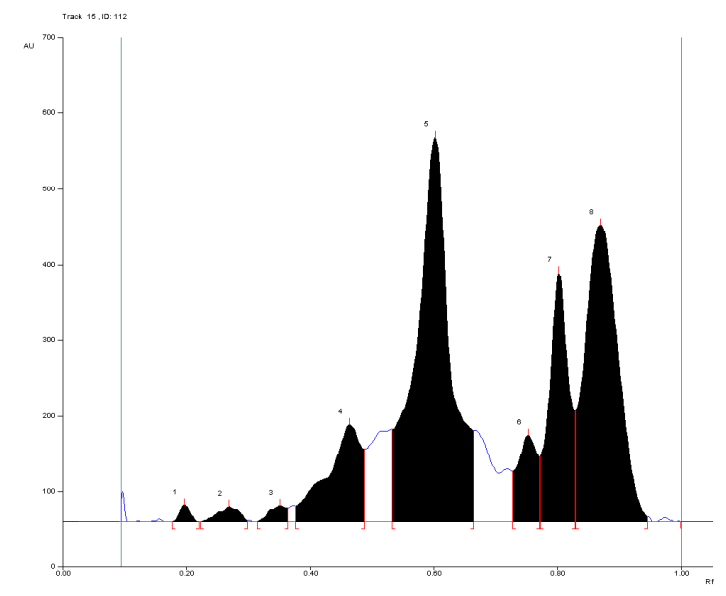


**10 $\mu$ l (298nm) (No: 112 -06 )**

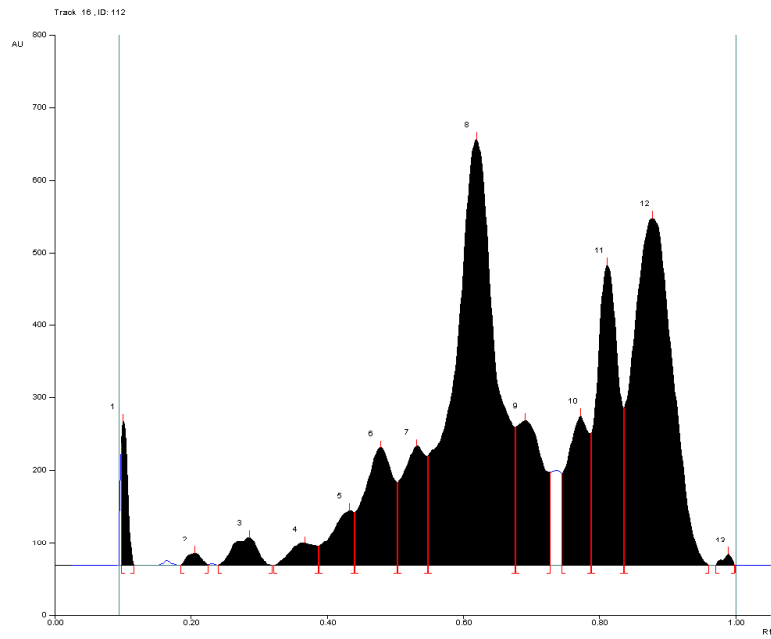
## Derivatisation (298nm)



## 298 nm 3D display (No: 112 -07 )

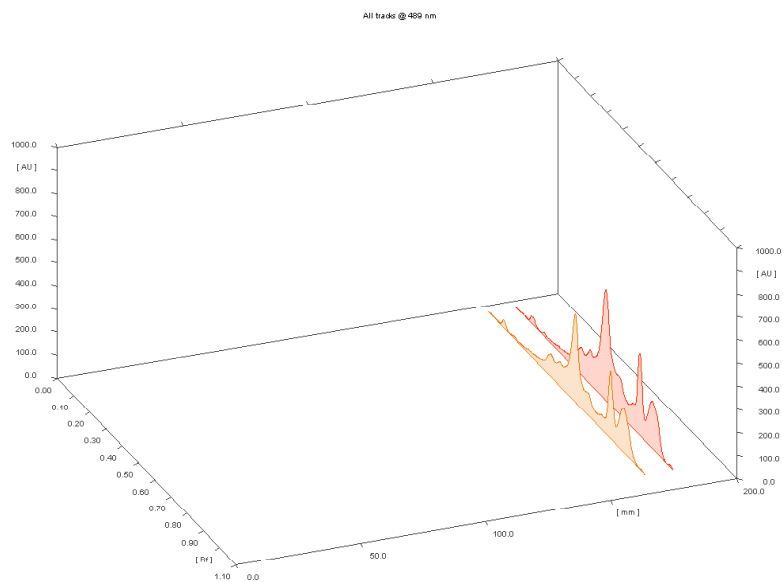


## Derivatisation 5µl (298nm) (No: 112 -08 )

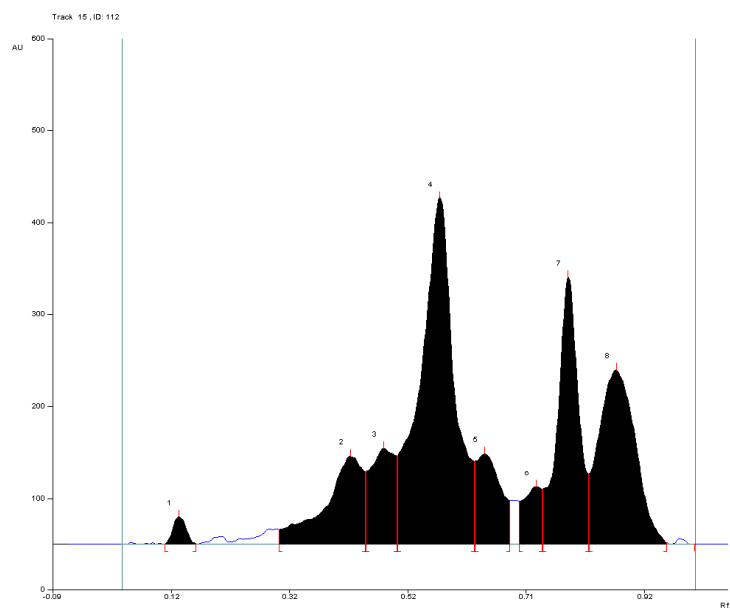


**Derivatisation 10 $\mu$ l (298nm) (No: 112 -09 )**

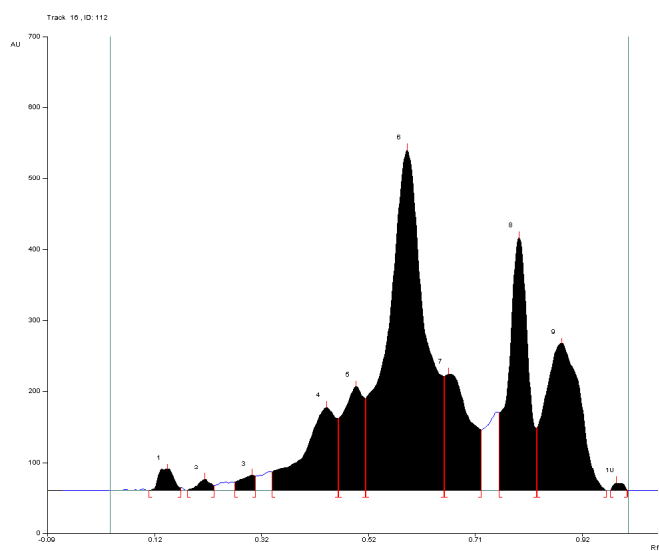
### Derivatisation (489nm)



**489 nm 3D display (No: 112 -10 )**

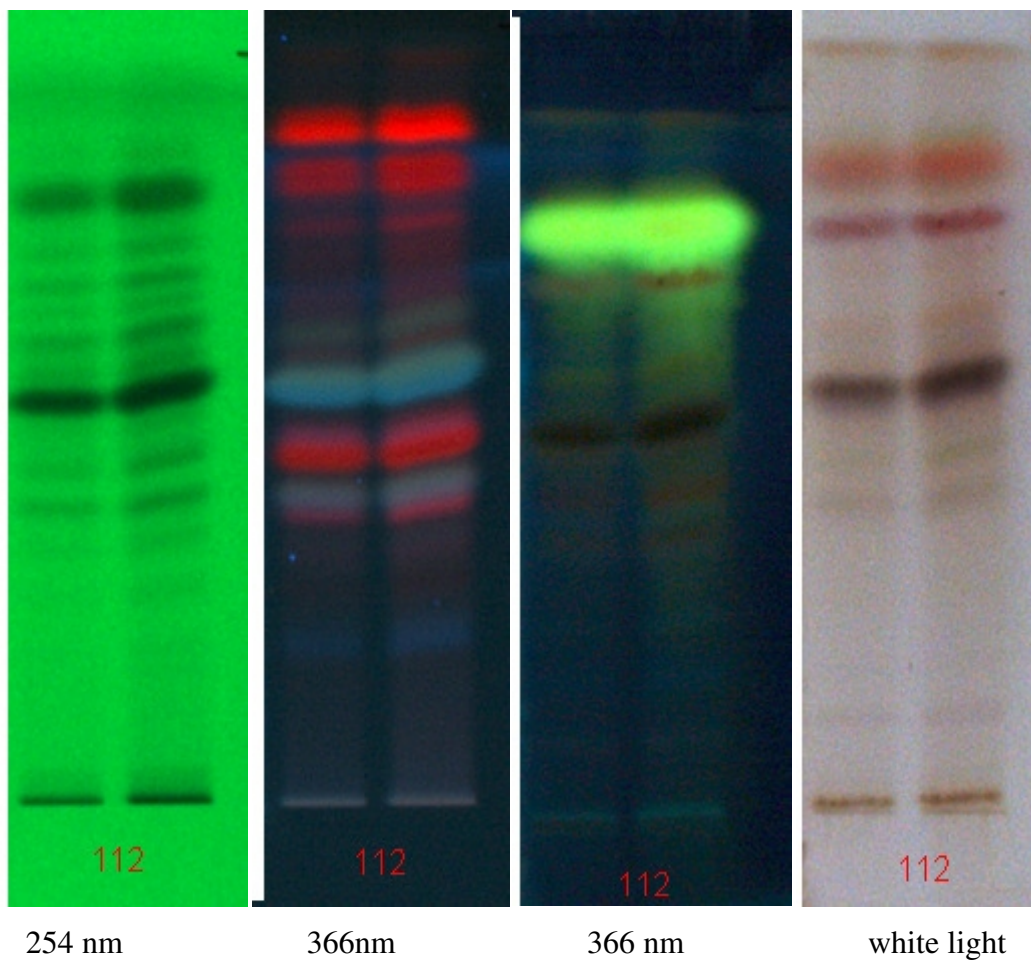


**Derivatisation 5 $\mu$ l (498nm) (No: 112 -11 )**



**Derivatisation 10 $\mu$ l (498nm) (No: 112 -12)**





## PHARMACOLOGICAL STUDIES OF ERAIPPU MATHIRAI

**Table 25. Effect of Eraippu Mathirai on isolated Guinea pig ileum preparation**

S. No	Dose of Histamine ( $\mu\text{g/ml}$ )	Percent of maximum response	
		<i>Histamine alone</i>	<b>Histamine+ Eraippu Mathirai (1mg/ml)</b>
1	10	2.2 $\pm$ 0.2	1.1 $\pm$ 0.1
2	20	3.2 $\pm$ 0.3	1.4 $\pm$ 0.2
3	40	4.2 $\pm$ 0.2	2.2 $\pm$ 0.2
4	80	5.0 $\pm$ 0.5	2.7 $\pm$ 0.3

Values are expressed in mean  $\pm$  SEM, \* $p < 0.05$  compared with histamine induced contraction (50mm as 100%); n=3.

**Table-26: Bronchodilator effect of Eraippu Mathirai on Histamine induced Bronchoconstriction.**

Treatment	Pre-Treatment Exposition in seconds	Post-Treatment Exposition in seconds	Percentage Protection
Eraippu Mathirai 100mg/kg. p.o.	100.12 $\pm$ 3.40	128.24 $\pm$ 4.09	21.92%
Eraippu Mathirai 200mg/kg. p.o.	105.16 $\pm$ 3.46	137.12 $\pm$ 4.28*	23.42%
Eraippu Mathirai 400mg/kg. p.o.	98.22 $\pm$ 4.58	144.34 $\pm$ 4.71*	31.95%
Promethazine (300mg/kg, p.o)	102.10 $\pm$ 5.15	162.42 $\pm$ 5.00*	37.13%

N=6; Values are expressed as mean  $\pm$  SEM; \*Significant between pre and post treatment time (Student's -t') \* $P < 0.01$ .

Fig 2.

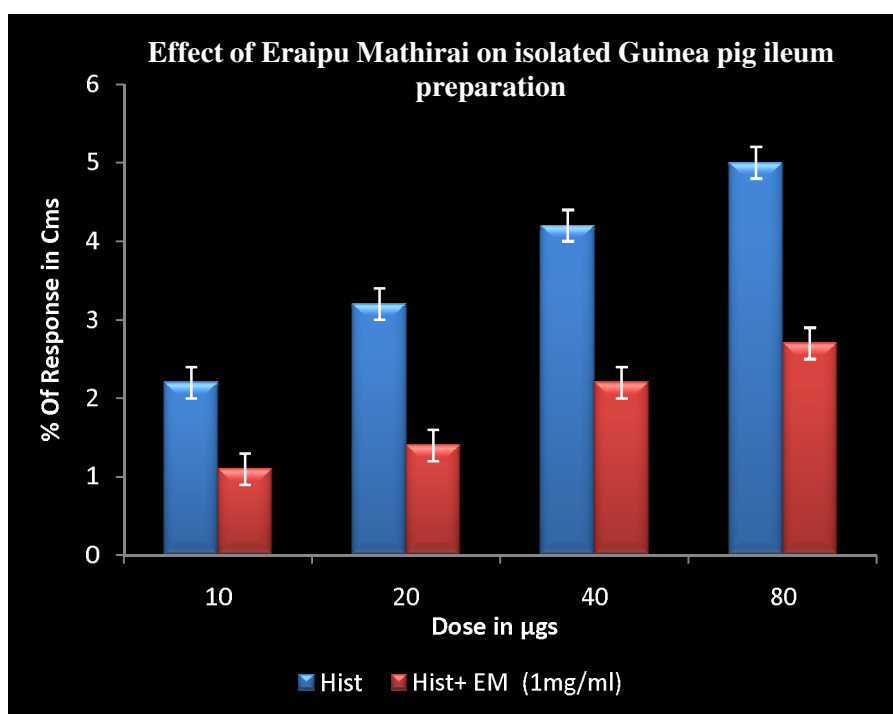
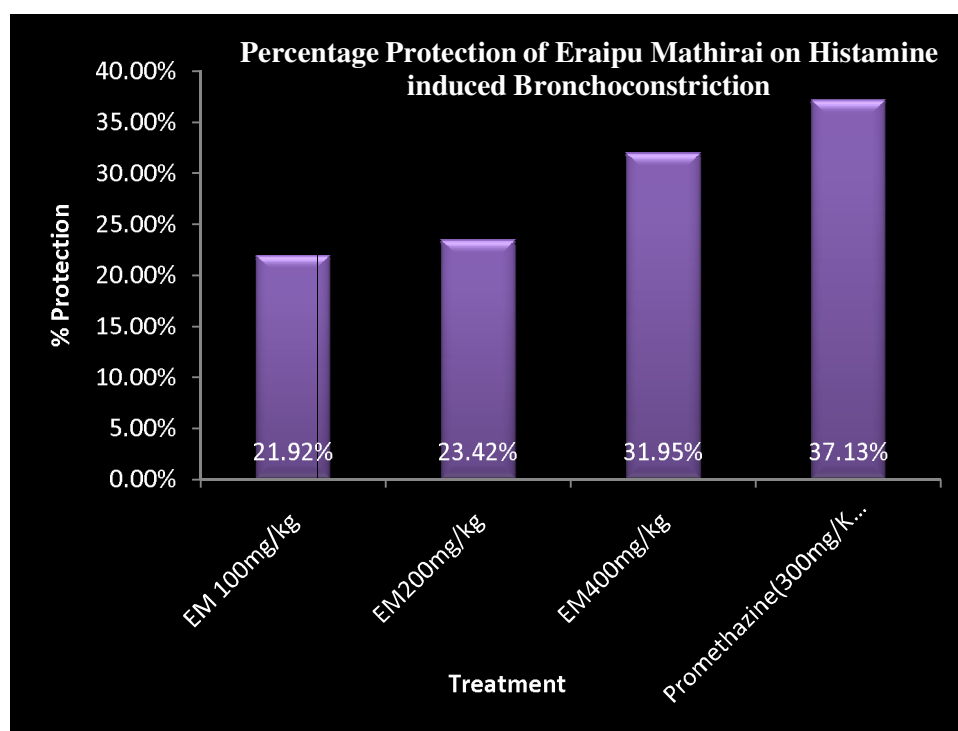


Fig 3.



**Table 27: Dose finding experiment and its behavioral Signs of Toxicity**

No	Dose mg/kg	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
1	1000	+	-	-	+	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	2000	+	-	-	+	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3	4000	+	-	-	+	-	+	+	+	-	-	-	-	+	-	-	-	+	+	-	-

1. Alertness 2. Aggressiveness 3. Pile erection 4. Grooming 5. Gripping 6. Touch Response 7. Decreased Motor Activity 8. Tremors 9. Convulsions 10. Muscle Spasm 11. Catatonia 12. Muscle relaxant 13. Hypnosis 14. Analgesia 15. Lacrimation 16. Exophthalmos 17. Diarrhoea 18. Writhing 19. Respiration 20. Mortality

**Table 28. Body wt (g) of rats exposed to *Eraippu Mathirai* for 28days.**

Dose (mg/kg/day)	Days		7	14	21	28
	1					
Control	119.24±4.88		122.49±5.12	114.15±5.02	118.10±6.14	122.74±5.41
100	121.60±5.12		126.55±5.66	122.00±5.51	124.38±5.44	127.01±6.00
200	126.56±5.00		128.34±5.10	130.22±4.63	133.36±4.18	136.32±6.21
400	120.24±4.20		124.19±5.61	128.18±5.46	132.42±5.07	124.11±5.20

Values are mean ± S.E.M. (Dunnet't' test). <sup>ns</sup>P<0.05; N=6.

**Table 29. Food intake of rats exposed to *Eraippu Mathirai* for 28days.**

Dose (mg/kg/day)	Days (gms/rats)				
	1	7	14	21	28
<b>Control</b>	42.14±2.40	45.21±2.53	47.00±2.46	46.74±2.75	46.42±3.00
<b>100</b>	45.05±2.95	45.00±2.61	45.17±2.72	47.26±2.88	47.28±3.17
<b>200</b>	43.44±2.20	44.19±2.54	44.00±2.84	45.04±3.00	46.12±3.53
<b>400</b>	43.00±2.24	45.31±2.77	46.67±2.99	46.26±2.46	47.59±3.00

Values are mean ± S.E.M. (Dunnet't' test). <sup>ns</sup>P<0.05; N=6.

**Table 30. Water intake of rats exposed to *Eraippu Mathirai* for 28days.**

Dose (mg/kg/day)	Days(ml/rat)				
	1	7	14	21	28
<b>Control</b>	48.55±2.76	50.45±3.64	53.15±3.27	52.44±3.26	51.00±3.11
<b>100</b>	50.45±2.58	52.18±3.14	55.10±3.12	52.10±3.12	40.55±2.90
<b>200</b>	52.19±2.98	51.24±3.72	50.46±3.00	48.14±2.78	41.10±3.34
<b>400</b>	52.00±3.12	54.33±3.12	53.64±3.75	54.22±3.14	45.23±3.56

Values are mean ± S.E.M. (Dunnet't' test). <sup>ns</sup>P<0.05; N=6.

**Table 31. Hematological parameters after 28days treatment with *Eraippu Mathirai*.**

Parameter	Control	100 mg/kg	200 mg/kg	400 mg/kg
<b>RBC (mm<sup>3</sup>)</b>	5.34±0.98	4.38±0.72	5.10±0.88	5.46±0.69
<b>HB (%)</b>	14.14±1.23	15.45±1.46	14.18±1.28	14.10±1.33
<b>Leukocyte (x10<sup>6</sup>/mL)</b>	12.8±1.22	10.5±1.14	10.1±1.10	10.6±1.21
<b>Platelets/μl</b>	1424±33.10	1335±30.25	1244±25.13**	1305±24.18*
<b>MCV (gl)</b>	53.10±3.12	52.24±3.14	50.27±4.00	53.23±3.82
<b>Neutrophil</b>	56.10±5.02	51 ±3.8	50.24±3.5	53.12±3.6
<b>Lymphocyte</b>	42.51±2.88	45.0±3.0	44.11±3.2	45.2±3.4
<b>Monocyte</b>	4.2±0.31	4.1±0.28	4.4±0.30	4.5±0.4
<b>Eosinophil</b>	1.00±0.00	1.0±0.22	1.0±0.11	1.00±0.11
<b>Basophil</b>	0	0	0	0
<b>ESR(mm)</b>	1±00	1±00	1±00	1±00
<b>PCV</b>	43.45±3.5	44.0±3.7	43.5±2.8	42.12±2.2

Values are mean ± S.E.M. (Dunnet't test). \*P<0.05; \*\*P<0.01. N=6.

**Table 32. Effect of treatment with *Eraippu Mathirai* biochemical parameters.**

<b>Dose (mg/kg)</b>	<b>Control</b>	<b>100 mg/kg</b>	<b>200 mg/kg</b>	<b>400 mg/kg</b>
<b>Total Bilirubin (mg/dL)</b>	0.64±0.06	0.62±0.04	0.62±0.05	0.67±0.04
<b>Bilirubin direct (µg/dL)</b>	11.12±1.24	11.45±1.36	10.11±1.48	10.10±0.88
<b>ALP (IU/L)</b>	60.22±4.12	61.10±5.2	59.75±5.0	62.5±4.46
<b>SGOT (U/L)</b>	89.64±6.1	92.54±5.79	85.82±6.00	90.10±6.14
<b>SGPT(U/L)</b>	71.02±6.2	70.45±5.8	72.02±6.00	75.21±5.79
<b>Total Protein(g/dl)</b>	8.24±1.28	7.10±0.22	8.00±0.25	8.03±0.26
<b>Albumin(g/dl)</b>	3.33±0.27	3.46±0.30	3.55±0.29	3.15±0.10
<b>Globulin(g/dl)</b>	5.64±0.22	5.48±0.25	4.74±0.24*	4.44±0.20**

Values are mean ± S.E.M. (Dunnet't' test). \*P<0.05; \*\*P<0.01. Vs. control group N=6.

**Table-33 RFT**

Dose (mg/kg)	Control	100 mg/kg	200 mg/kg	400 mg/kg
Urea(mg/dL)	53.04±1.77	54.00±3.21	55.32±2.82	53.12±1.42
Creatinine (mg/dL)	0.72±0.05	0.74±0.05	0.72±0.04	0.75±0.05
Uric acid (mg/dL)	1.4±0.10	1.2±0.10	1.5±0.15	1.4±0.14
Na m.mol	132.21±5.00	140.4±5.12	142.23±5.34	144.12±5.43
K m.mol	20.17±1.78	19.31±1.75	20.44±1.30	20.41±2.52
Cl m.mol	102.11±4.00	104.31±4.82	104.61±4.27	102.41±5.56

Values are mean ± S.E.M. (Dunnet' t' test). <sup>ns</sup>P<0.05; N=6.

**Table-34. Lipid Profile**

Dose (mg/kg)	Control	100 mg/kg	200 mg/kg	400 mg/kg
Total cholestrol(mg/dL)	44.15±2.88	42.17±2.64	44.21±3.00	43.91±3.12
HDL(mg/dL)	13.46±1.52	13.37±1.48	13.20±1.39	13.17±1.76
LDL(mg/dL)	42.21±2.72	43.16±2.48	42.00±3.46	43.00±3.55
VLDL(mg/dl)	15.43±2.91	15.56±2.74	16.10±1.88	15.46±1.64
Triglycerides (mg/dl)	84.10±3.19	83.24±2.70	84.20±3.13	86.74±2.98
Blood glucose (mg/dl)	122.10±6.22	124.18±5.13	125.29±5.00	126.46±2.88

Values are mean ± S.E.M. (Dunnet' t' test). <sup>ns</sup>P<0.05; N=6.



**Table-35 Urine Analysis**

Parameters	Control	100 mg/kg	200 mg/kg	400 mg/kg
<b>Colour</b>	Yellow	Yellow	Yellow	Yellow
<b>Transparency</b>	Clear	Slightly turbid	Slightly cloudy	Slightly turbid
<b>Specific gravity</b>	1.010	1.010	1.010	1.010
<b>PH</b>	>7.2	>8.0	>8.0	>9.0
<b>Protein</b>	Nil	3+	3+	3+
<b>Glucose</b>	Nil	Nil	Nil	Nil
<b>Bilirubin</b>	-ve	-ve	-ve	-ve
<b>Ketones</b>	-ve	+ve	+ve	+ve
<b>Blood</b>	Absent	Absent	Absent	Absent
<b>Urobilinogen</b>	Normal	Abnormal	Abnormal	Abnormal
<b>Pus cells</b>	0-cells/HPF	1-cell/HPF	2-cells/HPF	1-cell/HPF
<b>RBCs</b>	Nil	Nil	0-1cells/HPF	Nil
<b>Epithelial cells</b>	Nil	1-cell/HPF	Nil	1-cell/HPF
<b>Crystals</b>	Nil	Nil	Nil	Nil
<b>Casts</b>	Nil	Nil	Nil	Nil
<b>Others</b>	Bacteria seen	Bacteria seen	Bacteria seen	Bacteria seen

**Table 36. Effect of Eraippu Mathirai on organ weight**

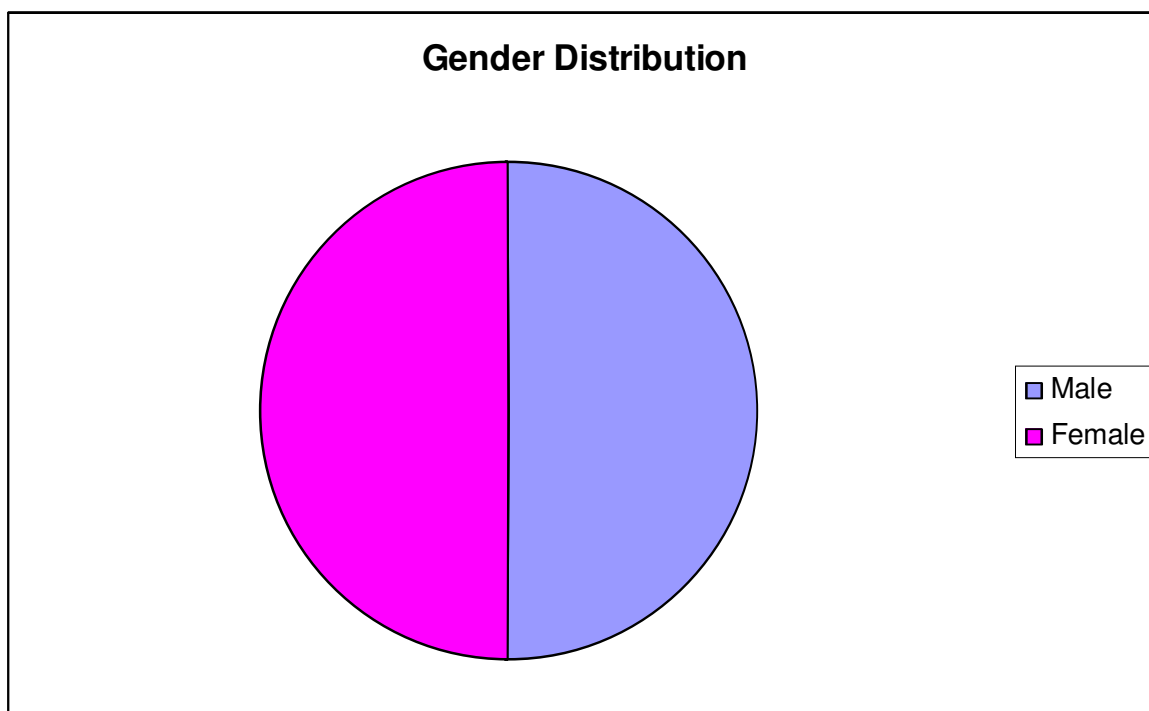
<b>Organs/Dose (mg/kg)</b>	<b>Control</b>	<b>100 mg/kg</b>	<b>200 mg/kg</b>	<b>400 mg/kg</b>
<b>Liver (g)</b>	9.44±0.42	8.50±0.32	8.11±0.20*	8.45±0.24
<b>Heart (g)</b>	0.35±0.02	0.35±0.02	0.34±0.02	0.35±0.02
<b>Lung (g)</b>	1.78±0.13	1.70±0.04	1.72±0.10	1.62±0.04
<b>Spleen (g)</b>	0.91±0.05	0.90±0.04	0.88±0.04	0.84±0.05
<b>Ovary (g)</b>	1.54±0.10	1.62±0.12	1.60±0.14	1.61±0.11
<b>Testes (g)</b>	1.96±0.05	1.98±0.06	1.92±0.04	2.79±0.05**
<b>Brain (g)</b>	2.00±0.03	1.98±0.03	1.94±0.03	1.92±0.04
<b>Kidney (g)</b>	0.67±0.04	0.65±0.04	3.66±0.04	0.67±0.05
<b>Stomach (g)</b>	1.32±0.15	1.33±0.15	1.34±0.14	1.32±0.10

Values are mean ± S.E.M. (Dunnett's test). \*P<0.05; \*\*P

## ERAIPPU NOI

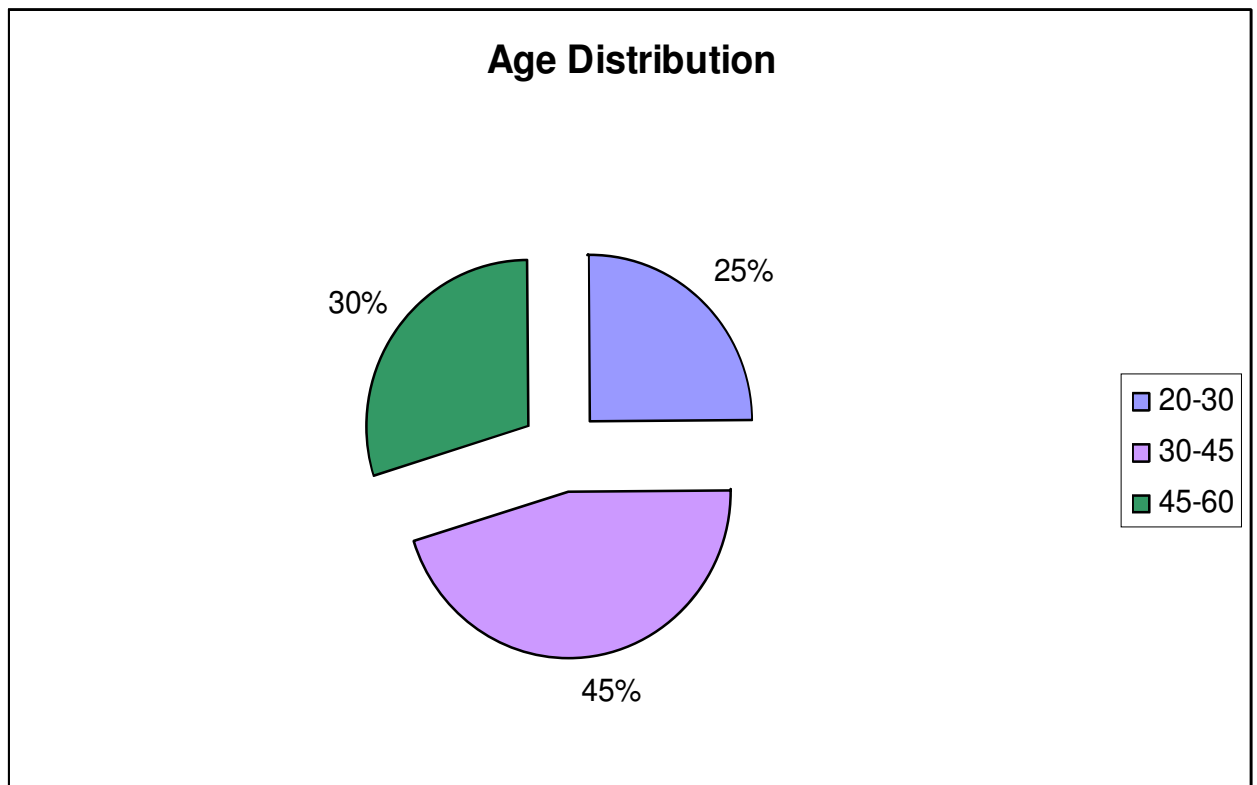
### Gender Distribution

Sno	Gender	No of Patients	Percentage
1	Male	10	50%
2	Female	10	50%



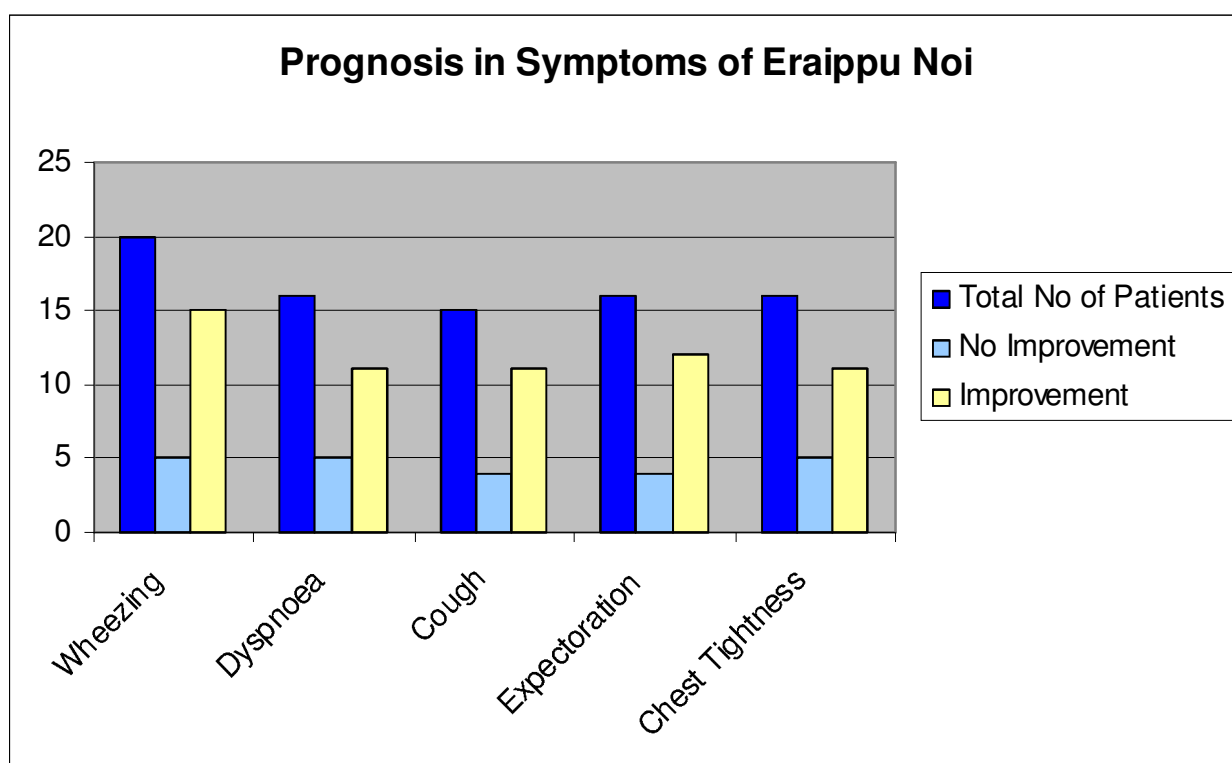
## AGE DISTRIBUTION

Sno	Age Range	No of Patients	Percentage
1	20-30	5	25%
2	30-45	9	45%
3	45-60	6	30%



**Table 37. Prognosis in Symptoms of Eraippu**

Sno	Symptoms	No of Patients before Treatment	No of Patients After Treatment		Percentage Improvement
			No Improvement	Improvement	
1	Wheezing	20	5	15	75%
2	Dyspnoea	16	5	11	69%
3	Cough	15	4	11	73%
4	Expectoration	16	4	12	75%
5	Chest Tightness	16	5	11	69%



**Table 38. Improvement in Peak Expiratory Flow Rate**

Sno	OPD/IPD No	BTPEFR	ATPEFR
1	C83886	180	220
2	C73336	160	230
3	C84796	150	210
4	C84977	200	250
5	B54391	170	200
6	C18860	210	220
7	C89810	220	240
8	C90162	160	180
9	C90610	230	230
10	C82390	190	220
11	C92700	200	240
12	C92885	170	170
13	B31179	220	250
14	C94024	230	250
15	C89598	190	190
16	4199	180	200
17	4210	160	190
18	5180	200	200
19	5196	220	290
20	5224	190	190

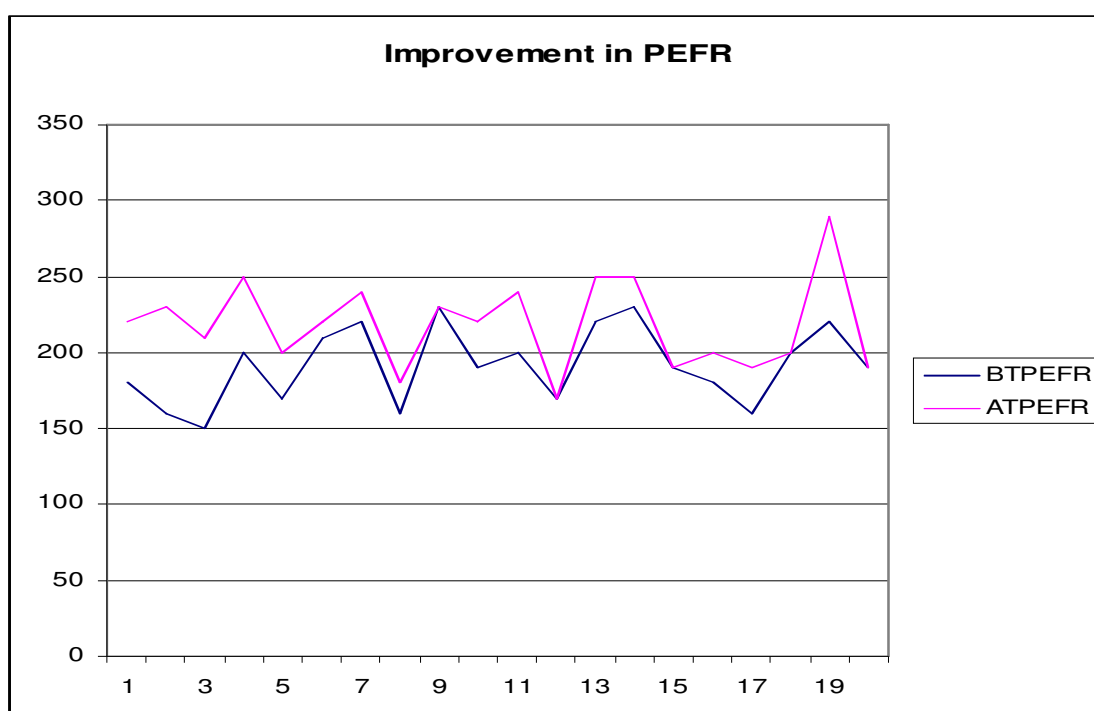


Table 39. Asthma Symptoms Table

Sno	OPD/IPD No	Name	Age	Sex	BTW	ATW	BTd	ATD	BTC	ATC	BTE	ATE	BTCT	ATCT
1	C83886	Lakshmi	35	F	+	-	+	-	-	-	+	-	+	-
2	C73336	Amudha	33	F	+	-	+	+	+	-	-	-	+	+
3	C84796	Fathima	26	F	+	-	+	-	+	-	+	+	-	-
4	C84977	Murugan	28	M	+	-	+	+	+	-	-	-	+	-
5	B54391	Sasikala	58	F	+	-	+	-	-	-	+	-	+	+
6	C18860	Thompson	60	M	+	+	+	-	+	-	+	+	+	-
7	C89810	Haridos	41	M	+	-	+	-	+	-	-	-	+	-
8	C90162	Kalaiselvi	29	F	+	+	+	+	-	-	+	-	+	+
9	C90610	Asokan	47	M	+	+	-	-	+	-	-	-	+	-
10	C82390	Devi	40	F	+	-	+	-	+	+	+	-	+	-
11	C92700	Srinivasan	39	M	+	-	+	+	+	-	+	-	-	-
12	C92885	Hemalatha	42	F	+	+	-	-	+	+	+	-	+	-
13	B31179	Hariharan	39	M	+	-	+	-	+	-	+	-	+	-
14	C94024	Sampanthan	42	M	+	+	+	-	+	-	+	+	+	+
15	C89598	Riswana	24	F	+	-	+	-	+	+	+	-	-	-
16	4199	Dhanam	36	F	+	-	+	-	-	-	+	-	+	-
17	4210	Eshwari	49	F	+	-	-	-	+	-	+	+	+	+
18	5180	Radha	52	M	+	-	+	-	-	-	+	-	+	-
19	5196	Sundar	24	M	+	-	+	+	+	-	+	-	-	-
20	5224	Chinnathambi	65	M	+	-	-	-	+	+	+	-	+	-

BT C Before Treatment Cough      AT E After Treatment Expectoration      W CT Wheezing Chest Tightness      D Dyspnoea

### Table 40. Investigations Before Treatment

Sl O	SH OPD/IPD No	Name	Age Sex	TC	DC			TRB C	ESR		PLT	AEC	AFB	BLOOD SUGAR		URE A	CREATI inine	TOTAL CHOLE STROL	SGOT	SGP T	ALP	L PROT EIN	CALC IUM	PHOSP ORO US	URINE		URINE DEPOSITS		
					P	L	E		1/2 hrs	1 hr				F	PP										Albu min	Sugar	Pus Cells	Epi Cells	
1	C83886	Lakshmi	35 F	15	14100	80	15	5	5.2	4	32	2.3	452 (c)		101	136	14	0.4	165	10	12	150	7.2	9	3	Nil	Nil	10-12	8-10
2	C73336	Amudha	33 F	12	6100	75	20	5	4.4	30	64	2.1	310 (c)		86	110	30	0.8	145	11	12	150	6.3	11.6	3.6	Nil	Nil	3-4	2-3
3	C84796	Fathima	26 F	14	10000	50	45	5	5.4	2	6	3.1	522 (c)		111	126	20	0.8	128	29	36	182	7.4	10.1	3.5	Nil	Nil	1-2	1-2
4	C84977	Murugan	28 M	17	11800	50	36	14	5.6	2	4	2.6	1055 (c)		91	119	19	0.6	149	22	33	146	7.2	9.5	2.9	Nil	Nil	2-3	2-3
5	B54391	Sasikala	58 F	12	9000	52	44	4	3.9	6	18	2.7	422 (c)		120	142	26	0.8	229	19	20	156	7.5	11.6	4.3	Nil	Nil	2-3	2-3
6	C18960	Thompson	60 M	17	5200	70	25	5	5.3	2	4	2.8	262 (c)		115	150	22	0.7	223	16	20	160	6.2	11	3	Nil	Nil	2-4	2-4
7	C89810	Haridos	41 M	15	6900	60	33	7	4.9	2	4	2.2	300 (c)		101	124	16	0.5	122	14	16	146	7	11	3	Nil	Nil	2-6	3-4
8	C90162	Kalaiselvi	29 F	14	6800	62	32	6	5.2	4	14	2.9	244 (c)		83	93	21	0.6	176	16	17	145	5.1	11.1	3.1	Nil	Nil	1-2	1-2
9	C90610	Asokan	47 M	17	12300	80	17	3	5.7	2	4	2.3	377 (c)		110	144	24	0.7	261	24	25	150	7.7	11	3.1	Nil	Nil	1-2	1-2
10	C82390	Devi	40 F	14	7700	60	36	4	4.7	4	8	2.1	308 (c)		103	121	14	0.4	200	19	20	158	7	10	3	Nil	Nil	1-2	1-2
11	C92700	Srinivasan	39 M	14	5700	50	41	9	4.8	4	8	2.6	444 (c)		109	136	28	0.7	203	52	45	234	7.5	10	3	Nil	Nil	2-3	2-3
12	C92885	Hemalatha	42 F	12	9400	56	38	6	3.8	12	34	4.3	400 (c)		90	124	15	0.4	148	30	32	175	7	10.4	3	Nil	Nil	2-4	2-4
13	B31179	Hariharan	39 M	15	9700	40	55	5	5	4	12	3.2	385 (c)		68	98	15	0.6	117	32	29	206	7.3	10.3	4.5	Nil	Nil	2-4	1-2
14	C94024	Sampanthan	42 M	15	9800	64	33	3	5	30	54	3.3	433 (c)		88	123	25	0.8	188	30	31	236	7	11.1	2.8	Nil	Nil	2-4	1-2
15	C89598	Riswana	24 F	12	9900	60	34	6	6.2	2	10	3.7	390 (c)		93	106	27	0.7	166	16	18	151	7	10.6	3.2	Nil	Nil	1-2	1-2
16	4199	Dhanam	36 F	15	7900	70	26	4	5.2	6	18	3.8	211 (c)		116	135	23	0.6	151	23	25	155	6.6	10.1	3	Nil	Nil	1-2	1-2
17	4210	Eshwari	49 F	11	10100	55	40	5	4.1	20	44	4.1	211 (c)		92	125	18	0.6	203	14	16	171	6.1	10.4	3.1	Nil	Nil	4-8	8-10
18	5180	Radha	52 M	16	7400	67	30	3	4.5	2	4	2.3	156 (c)		88	105	16	0.5	128	12	14	150	6	10.9	3.1	Nil	Nil	2-6	2-5
19	5196	Sundar	24 M	15	9300	60	28	12	5.5	2	4	3.7	388 (c)		80	102	18	0.5	157	25	27	189	6.1	10.9	3.2	Nil	Nil	2-4	3-6
20	5224	Chinnathambi	65 M	13	11000	50	36	14	5.4	4	10	2.7	711 (c)		105	119	20	0.6	167	13	15	183	5.6	10	2.8	Nil	Nil	2-4	2-4



Table 41. Investigations After Treatment

SNO	OPD / IPD NO	NAME	AGE SEX	HB	TC		DC		TRBC		ESR		AEC		BLOOD		CREATININE	TOTAL CHOL		SG		TOTAL PROTEIN	CALCIUM	PHOSPHOROUS	URINE		URINE	
					P	L	E	1/2 hrs	1 hr	PLT	F	PP	OT	PT	ALP													
1	C83886	Lakshmi	35 F	14.9	13900	66	30	4	5.1	4	10	2.3	350	96	140	15	0.5	152	12	13	146	7.3	10	3.2	Nil	Nil	8-9	7-9
2	C73336	Amudha	33 F	12.4	6200	44	52	4	4.2	6	12	2.2	362	89	115	29	0.6	172	10	14	158	6.2	11.5	3.4	Nil	Nil	3-5	2-3
3	C84796	Fathima	26 F	12.9	10100	50	45	5	5.3	4	10	3.2	290	115	110	18	0.7	135	30	39	162	7.3	10.5	3.6	Nil	Nil	2-3	2-3
4	C84977	Murugan	28 M	15.6	11600	53	34	13	5.5	2	4	2.5	811	100	105	22	0.5	152	24	46	152	7.1	9.2	3.1	Nil	Nil	2-4	1-2
5	B54391	Sasikala	58 F	12	9100	70	26	4	3.6	4	10	2.6	267	110	130	25	0.7	200	23	25	148	6.9	11.3	4.5	Nil	Nil	2-3	2-4
6	C18860	Thompson	60 M	15.9	5400	44	52	4	5.4	2	3	2.9	280	109	145	24	0.7	192	22	35	156	5.9	11.3	3.2	Nil	Nil	3-5	2-5
7	C89810	Haridos	41 M	15.2	7000	80	14	6	5	2	4	2.1	133	110	125	15	0.6	130	17	20	140	6.4	10.9	3.3	Nil	Nil	2-3	2-3
8	C90162	Kalaiselvi	29 F	13	6600	62	33	5	5.6	2	6	3	155	90	96	24	0.7	156	18	19	143	5.4	10.7	3	Nil	Nil	3-4	2-3
9	C90610	Asokan	47 M	16.5	12100	57	40	3	5.2	2	4	2.4	77	95	150	29	0.5	240	26	20	165	7.6	10.5	2.9	Nil	Nil	1-2	1-2
10	C82390	Devi	40 F	14.3	7800	66	30	4	4.5	2	4	2.2	267	98	135	16	0.4	210	24	15	157	6.8	10.2	2.7	Nil	Nil	2-4	1-2
11	C92700	Srinivasan	39 M	14.7	5800	47	48	5	4.7	2	6	2.5	188	111	140	30	0.6	190	62	40	225	6.6	9.8	3.5	Nil	Nil	2-3	2-3
12	C92885	Hemalatha	42 F	12.2	9600	48	46	6	3.5	4	10	4.2	288	95	120	17	0.5	128	35	26	165	7.2	10	2.5	Nil	Nil	2-5	3-4
13	B31179	Hartharan	39 M	14.4	9500	60	36	4	4.9	2	4	3.5	211	76	110	15	0.4	97	26	25	196	6.5	9.7	3.9	Nil	Nil	2-3	1-3
14	C94024	Sampanthan	42 M	13.9	9100	75	20	5	5.2	4	10	3.1	222	96	125	26	0.7	170	28	36	246	7.3	11.5	3.2	Nil	Nil	2-4	2-3
15	C89598	Riswana	24 F	10.9	9600	55	30	5	6.4	2	6	3.6	296	106	115	28	0.8	152	25	20	131	7.7	9.9	2.9	Nil	Nil	1-2	1-2
16	4199	Dhanam	36 F	15	8000	60	36	4	5.4	6	12	3.7	56	104	145	20	0.7	166	25	30	154	6.2	10.4	3.5	Nil	Nil	1-3	1-2
17	4210	Eshwari	49 F	11.2	9900	45	50	5	4.6	4	10	4.5	168	100	135	20	0.6	182	23	32	151	5.9	10.2	2.7	Nil	Nil	4-7	7-9
18	5180	Radha	52 M	15.5	7500	60	35	5	4.2	2	4	2.5	122	86	115	17	0.4	145	19	16	160	5.5	10.7	2.6	Nil	Nil	2-5	2-3
19	5196	Sundar	24 M	14.8	9200	76	18	6	5.3	2	4	3.1	1500	72	112	22	0.5	152	20	29	179	5.2	11.3	3.5	Nil	Nil	2-3	3-5
20	5224	Chinnathambi	65 M	12.8	11100	50	60	10	5.1	2	8	2.8	646	115	115	25	0.8	166	15	17	175	5.8	10	2.3	Nil	Nil	2-3	2-3

## Eraippu Noi (Bronchial Asthma)

### Statistical Analysis:

All collected data were entered into MS Excel software using different columns as variables and rows as patients. SPSS software was used to perform statistical analysis. Basic descriptive statistics include frequency distributions and cross-tabulations were performed. The quantity variables were expressed as Mean  $\pm$  Standard Deviation and qualitative data as percentage. A probability value of  $<0.05$  was considered to indicate as statistical significance. Paired 't' test was performed for determining the significance between before and after treatment.

**Table 42. Paired t test for Symptoms before and after treatment:**

Variable	Obs	Mean	Std.dev	t.value	P value
Before symptoms	20	4.15	0.489	13.784	P<0.0001
After symptoms	20	1.15	0.933		

For symptoms:

Mean  $\pm$  Standard deviation before treatment is 4.15 and after treatment is 1.15, which is statistically significant ( $p<0.0001$ ).

**Table 43. Paired t test for PEFr before and after treatment:**

Variable	Obs	Mean	Std.dev	t.value	P value
Before symptoms	20	191.5	24.979	-5.311	P<0.0001
After symptoms	20	218.5	29.607		

For Peak expiratory flow rate:

Mean  $\pm$  Standard deviation before treatment is 191.5 and after treatment is 218.5, which is statistically significant ( $p<0.0001$ ).

**Table 44. Paired t test for AEC before and after treatment:**

<b>Variable</b>	<b>Obs</b>	<b>Mean</b>	<b>Std.dev</b>	<b>t.value</b>	<b>P value</b>
<b>Before symptoms</b>	20	399.05	198.514	-.988	0.336
<b>After symptoms</b>	20	334.45	327.681		

For Absolute eosinophil count:

Mean  $\pm$  Standard deviation before treatment is 399.05 and after treatment is 334.45, which is statistically significant (p=0.336).

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Title: Pre-clinical and clinical study on kuzhpaanda choozanam for "styptic activity" in the management of Perumbadu (Menorrhagia)  
No. NIS/IEC/2011/3/15a - 24/12/2011

## DECISION

Opinion of the Institutional Ethics Committee – Please Check one

☒ Approval

☐ Modifications required prior to approval (Please specify one space below)

☐ Disapproval

Date of review: \_\_\_\_\_

K. Manickavasagam  
(Dr. K. MANICKAVASAGAM)  
Member Secretary

Signed: Dr. V. Subramanian (Please print name) Dr. V. SUBRAMANIAN  
chair person  
(Please delete as appropriate, Chairperson, Secretary)

Modifications needed

Modification given to candidate

The research proponent is hereby informed that the Institutional Ethics Committee will require the following:

1. All adverse drug reactions (ADRs) that are both serious and unexpected to be reported promptly to the IEC within 7 working days
2. The progress report to be submitted to the IEC atleast annually
3. Upon completion of the study, a final study status report needs to be submitted to the IEC

IAEC PROTOCOL NO : 1248/AC/04/C PCSEA / 4-15A/2011

CERTIFICATE

20/12/2011

This is certify that the project title Preclinical and clinical  
study on "kuzhpaanda chooranam" for septic activity in the  
management of Perumbadu [Menorrhagia].  
has been approved by the IAEC.

Prof. Dr. K. Marichavasa Kam  
Name of Chairman/Member Secretary IAEC:

Dr. B. Jayachandran Dare  
Name of CPCSEA nominee:

Signature with date

K. Marichavasa Kam

Chairman/Member Secretary of IAEC:

B. Jayachandran Dare

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(Kindly make sure that minutes of the meeting duly signed by all the  
participants are maintained by Office )



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Eraippu [Bronchial asthma].  
No. NIS/IEC/2011/3/156 - 24/12/2011

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☒ Approval

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☐ Disapproval

Date of review: \_\_\_\_\_

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(Please delee as appropriate, Chairperson, Secretary)

Modifications needed

Modification given to candidate

The research proponent is hereby informed that the Institutional Ethics Committee will require the following:

1. All adverse drug reactions (ADRs) that are both serious and unexpected to be reported promptly to the IEC within 7 working days
2. The progress report to be submitted to the IEC atleast annually
3. Upon completion of the study, a final study status report needs to submitted to the IEC



IAEC PROTOCOL NO : 1248/ac/04/CPCSEA/4-15B/2011

CERTIFICATE

20/12/2011

This is certify that the project title Pre clinical and clinical study  
on Eraippei Mathirai for bronchodilator activity in the  
management of Eraippu [Bronchial asthma].  
has been approved by the IAEC.

Prof. Dr. K. Marickavasakam  
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Dr. B. Jayachandran Dare  
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CPCSEA nominee:

(Kindly make sure that minutes of the meeting duly signed by all the  
participants are maintained by Office )

## CERTIFICATE

This is to certify that the project title: "Preclinical study on "Kuzhpaanda Chooranam" for Styptic Activity in the management of perumbadu (Menorrhagia)" has been approved by the IAEC with the reference number. XIII/VELS/PCOL/41/2000/CPCSEA/IAEC/08.08.12.

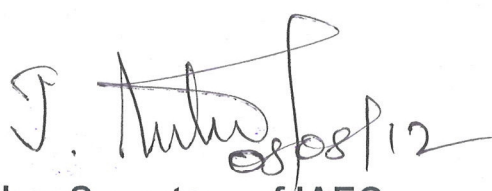
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Name of CPCSEA nominee:

Dr. K. Sadhasivan Pillai

**Signature with date**



**Member Secretary of IAEC**

**Dr. J. ANBU, M.Pharm., Ph.D., D.M.L.T., MBA**

**Professor & Head**

**Department of Pharmacology & Toxicology**

**School of Pharmaceutical Sciences**

**Vels University**

**Pallavaram, Chennai-600 117.**

## CERTIFICATE

This is to certify that the project title: "Preclinical study on "Eraippu Mathirai" for Bronchodilator Activity in the management of Eraippu (Bronchial Asthma)" has been approved by the IAEC with the reference number. XIII/VELS/PCOL/40/2000/CPCSEA/IAEC/08.08.12.

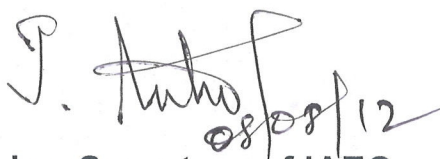
Name of Member Secretary IAEC:

Dr. J. Anbu

Name of CPCSEA nominee:

Dr. K. Sadhasivan Pillai

**Signature with date**



**Member Secretary of IAEC**

**Dr. J.ANBU, M.Pharm., Ph.D., D.M.L.T.,MBA.**  
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Department of Pharmacology & Toxicology  
School of Pharmaceutical Sciences  
Vels University  
Pallavaram, Chennai-600 117.





# The Tamil Nadu Dr. M.G.R. Medical University

69, Anna Salai, Guindy, Chennai-600 032

This Certificate is awarded to Dr/Mr/Ms ..... **S. SAVITHA** .....

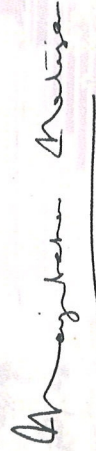
for participating as a ~~Resource~~ Person / Delegate in the II Workshop on

## "Introduction to Scientific & Medical Writing"

organized by the Department of Epidemiology,

The Tamil Nadu Dr. M.G.R. Medical University on 2nd December 2011.

This educational activity has been awarded **10 Credit Points**  
by the Centre for Accreditation, The Tamil Nadu Dr. M.G.R. Medical University.



**DR. MAYILVAHANAN NATARAJAN**

M.S.Orth. M.Ch.Orth. (L'pool) Ph.D. (Orth. Onco.) F.R.C.S. (Eng) D.Sc.

**7th VICE CHANCELLOR**



**Dr. SRILAKSHMI, DCH, Ph.D.**

REGISTRAR



**Dr. N. KABILAN, M.D. (Siddha)**

HOD, DEPT. OF EPIDEMIOLOGY